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(72) Inventeurs/Inventors:
VENKATARAMAN, BALA, US;
GUTHRIE, MICHAEL, US

(73) Propriétaires/Owners:
VENKATARAMAN, BALA, US;
GUTHRIE, MICHAEL, US

(74) Agent: SIM & MCBURNEY

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(54) Title: COMPOSITION AND METHOD FOR TREATING IRON DEFICIENCY ANEMIA

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A composition comprising heme iron and/or heme iron polypeptide in combination with ionic iron(s) and/or chelated iron(s). Administration of effective dosages of the present composition provides a method for treating and/or preventing iron deficiency anemia, and the physiological, biochemical, morphological, and behavioral manifestations symptomatic of same.

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(71) Applicants and
(72) Inventors: **VENKATARAMAN, Bala** [US/US]; 405 Gatehouse Court, Alpharetta, GA 30004 (US). **GUTHRIE, Michael** [US/US]; 2811 Ridge Drive, Grand Junction, CO 81506 (US).

(74) Agent: **DRUMMOND, Sandra**; Myers & Kaplan Intellectual Property Law, LLC, Cumberland Center II, 3100 Cumberland Blvd., Suite 1400, Atlanta, GA 30339 (US).

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(54) **Title:** COMPOSITION AND METHOD FOR TREATING IRON DEFICIENCY ANEMIA

(57) **Abstract:** A composition comprising heme iron and/or heme iron polypeptide in combination with ionic iron(s) and/or chelated iron(s). Administration of effective dosages of the present composition provides a method for treating and/or preventing iron deficiency anemia, and the physiological, biochemical, morphological, and behavioral manifestations symptomatic of same.

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# COMPOSITION AND METHOD FOR TREATING IRON DEFICIENCY ANEMIA

Be it known that I, BALA VENKATARAMAN, residing at 405 Gatehouse Court, Alpharetta, Georgia 30004, and I, MICHAEL GUTHRIE, residing at 2811 Ridge Drive, Grand Junction, Colorado 81506, citizens of the United States, have invented certain new and useful improvements in a Composition and Method for Treating Iron Deficiency Anemia of which the following is a specification.

## CROSS-REFERENCE AND PRIORITY CLAIM TO RELATED APPLICATION

This Patent Cooperation Treaty application claims priority to and the benefit of United States Non-Provisional patent application entitled "Composition and Method for Treating Iron Deficiency Anemia," filed September 19, 2005, on behalf of inventors Bala Venkataraman and Michael Guthrie, having assigned Serial No. 11/230,042.

## TECHNICAL FIELD

The present invention relates generally to nutritional supplements and disease treatment, and more specifically to a composition and method for treating iron deficiency anemia.

## BACKGROUND OF THE INVENTION

In the human body, iron is essential for the implementation and maintenance of several vital cellular functions and biosynthetic processes, including oxygen transport capabilities, aerobic cellular activity, intracellular electron transport, and integral enzymatic reactions within body tissue. Unfortunately, as a combined result of various socioeconomic conditions, environmental factors, genetic predispositions, and the collective dietary habits amongst the general populace, iron deficiency is the most common known form of nutritional deficiency amongst humans.

Of significant prevalence, especially amongst children and women (i.e., particularly pregnant women and/or women of childbearing age), is iron deficiency anemia, a condition defined by a gross reduction in overall iron levels in the red blood cells and, thus, a decline in hemoglobin synthesis, the molecule ultimately responsible for the transport and distribution of oxygen from the lungs to tissues of the body. Indeed, in pregnant women, iron deficiency increases both the risk of pre-term delivery and/or delivery of a low-birthweight baby, whereas with children, iron deficiency anemia may cause developmental delays, behavioral disturbances, altered growth patterns, and increased infections. Still other manifestations symptomatic of iron deficiency anemia may include pale skin tone

or color, headaches, extreme fatigue, light-headedness, glossitis (swelling of the tongue), koilonychias (spoon nails), and other overt, *albeit* extreme, behavioral disturbances, such as the consumption of dirt or clay (pica or geophagia), or the abnormal consumption of ice (pagophagia).

Accordingly, the maintenance, or bioavailability, of nutritionally adequate iron levels is largely a collective function of the composition of food consumed, the quantity and chemical form of iron contained therein, and the presence of food items that either promote or inhibit iron absorption. Specifically, iron is absorbed as either a heme iron (an intact metalloporphyrin ring), or nonheme iron (ionic iron). Heme iron, however, which is principally found in meat as hemoglobin or myoglobin, is more readily and effectively absorbed than nonheme iron and, thus, provides a significantly greater dietary source of iron than nonheme iron. Additionally, food items such as bran, wheat, soy and other cellulosic products, which seemingly have no influence on heme iron absorption, tend to appreciably inhibit nonheme iron absorption; thus, exposing vegetarians to a relatively greater risk of developing an iron deficiency.

In fact, as professed by the American Society for Clinical Nutrition, approximately 5%-35% of heme iron is absorbed from a single meal, whereas nonheme iron absorption from a single meal

can range from approximately 2% to 20%, depending on the iron status of the individual and the ratio of enhancers and promoters in the diet. Accordingly, although heme iron constitutes only approximately 10% of dietary iron intake, heme iron may provide up to one-third of overall *absorbed* dietary iron. Consequently, inadequate consumption of foods high in heme iron content, especially during periods of increased iron demand (i.e., gestational and/or lactational periods), deprives the body of a considerable percentage of necessary dietary iron. Unfortunately, whether due to staunch dietary habits or beliefs, or the unavailability of certain foods due to prevailing socioeconomic and/or geographic conditions, the consumption of foods low or deficient in heme iron content, or the strict consumption of nonheme iron foods, will likely result in iron deficiency anemia.

Accordingly, as an alternative to radical dietary adjustment, iron supplements have traditionally offered a more subtle, therapeutic approach to the treatment of iron deficiency. However, the efficacy of supplement intervention (i.e., total effective iron absorption) is dependent upon a number of factors, the most of germane of which is the composition of the supplement and the total iron dosage.

That is, various iron supplements are typically prescribed in doses containing between 40mg and 150mg of elemental iron per

day, wherein a higher dosage of iron results in greater overall absorption. However, a high dose of iron as a dietary supplement (or fortificant) is not without consequence. Indeed, many existing iron supplements cause distressing side effects, such as nausea, diarrhea, constipation and/or cramping; thus, resulting in patient non-compliance with the prescribed supplement regimen. Further, it has been strongly suggested that high single doses of iron may contribute to the elevated formation of highly reactive oxygen radicals and, thus, promote various pathogenic processes, such as cardiovascular disease.

Still other clinically-administered iron supplement preparations that contain iron salts, such as ferrous sulfate, (hydrated) ferrous gluconate, or ferrous fumarate, as the primary iron source, may actually provide less iron than otherwise expected. Specifically, although inconsequential to heme iron absorption, dietary supplementation with such ferrous salts effectively reduces nonheme iron absorption and, thus, offers a counter-intuitive approach to individuals whose already limited iron intakes are dependent upon a diet high in nonheme iron content (i.e., vegetarians, indigents, etc.).

Therefore, it is readily apparent that there is a need for a composition and method for treating iron deficiency anemia, wherein the composition accounts for dietary inconsistencies across the broad spectrum of patient demographic, and further

reduces, if not eliminates, the side effects associated with traditional iron supplements; thereby, increasing overall patient compliance. Accordingly, the composition of the present invention proffers such results through the combination of heme iron and/or heme iron polypeptide with ionic irons (i.e., iron salts) and/or chelated irons, wherein the combination provides a synergistic effect that substantially reduces the prescribed iron dosage, yet significantly increases overall iron absorption. There is a further need for such a composition that offers additional vitamins and minerals in conjunction with the prescribed iron content.

## BRIEF SUMMARY OF THE INVENTION

Briefly described, in a preferred embodiment, the present invention overcomes the above-mentioned disadvantages, and meets the recognized need for such an invention by providing a composition and method for treating iron deficiency anemia.

According to its major aspects and broadly stated, the present invention in its preferred form is a composition comprising ionic iron(s) and/or chelated iron(s) in combination with heme iron and/or heme iron polypeptide, wherein heme iron polypeptide is preferably in the form of a proteolytic digest of bovine and/or porcine hemoglobin; however, it should be recognized that other derivations of heme iron polypeptide may

be procured from the hemoglobin and/or myoglobin molecular complexes of alternate animal species. The ionic irons of the present composition are preferably in the form of soluble iron salts, but may further include, without limitation, slightly soluble iron salts and/or insoluble iron salts. Additionally, the chelated iron of the present composition may be selected from any one or more of the preferred complexes of iron polysaccharide, iron bis glycinate, and/or iron proteinate; although alternate chelated iron complexes are contemplated. In certain embodiments, the present composition further comprises vitamins and minerals, including, without limitation, folic acid, vitamin A, vitamin B (all series), vitamin C, vitamin D, vitamin E, calcium, magnesium, or the like, so as to provide a prenatal composition.

More specifically, the composition of the present invention may comprise any combination of the following amounts of the specific ingredients *(nota bene: all of the following amounts of iron are in terms of total elemental iron)*: heme iron or heme iron polypeptide, or a combination thereof, in an amount between about 2mg and about 12mg, and preferably between about 6mg and about 9mg; and, ionic iron(s) or chelated iron(s), or a combination thereof, in an amount between about 15mg and about 100mg, and preferably between about 20mg and about 75mg. The composition may further specifically comprise folic acid in an amount between about 0.1mg and about 5mg, and preferably between

about 0.4mg and about 2mg; and/or, vitamin B12 in an amount between about 1mcg and about 900mcg, and preferably between about 12mcg and about 500mcg.

In a preferred embodiment of the present invention, the composition comprises heme iron or heme iron polypeptide, or a combination thereof, in an amount of about 6mg (total elemental iron); and, ionic iron(s) or chelated iron(s), or a combination thereof, in an amount of about 21mg (total elemental iron), wherein the instant composition may further selectively comprise any one or more of the foregoing vitamins and minerals, including folic acid and/or vitamin B12 within the limits prescribed hereinabove.

In still another preferred embodiment of the present invention, the composition comprises heme iron or heme iron polypeptide, or a combination thereof, in an amount of about 12mg (total elemental iron); and, ionic iron(s) or chelated iron(s), or a combination thereof, in an amount of about 15mg (total elemental iron), wherein the instant composition may further selectively comprise any one or more of the foregoing vitamins and minerals, including folic acid and/or vitamin B12 within the limits prescribed hereinabove.

In yet another preferred embodiment of the present invention, the composition comprises heme iron or heme iron

polypeptide, or a combination thereof, in an amount of about 12mg (total elemental iron); and, ionic iron(s) or chelated iron(s), or a combination thereof, in an amount of about 63mg (total elemental iron), wherein the instant composition may further selectively comprise any one or more of the foregoing vitamins and minerals, including folic acid and/or vitamin B12 within the limits prescribed hereinabove.

In other embodiments of the present invention, various compositions may comprise heme iron and/or heme iron polypeptide in combination with ionic iron(s) and/or chelated iron(s), each in any amount, within the prescribed limits described hereinabove, or otherwise selected for effective treatment and/or prevention of iron deficiency anemia. As such, via administration of effective dosages of the present composition, the instant invention further includes methods for treating and/or preventing iron deficiency anemia, and the physiological, biochemical, morphological, and behavioral manifestations symptomatic of same. Furthermore, inclusion of the foregoing prenatal vitamins within the present composition further provides an effective vitamin supplement for pregnant females, wherein other measured compositions may further be utilized for nursing mothers during periods of increased iron demand (i.e., lactational periods).

According to another aspect, there is provided a composition for treating iron deficiency anemia, consisting essentially of:

heme iron polypeptide; and,

an iron material selected from the group consisting of ionic irons, chelated irons selected from the group consisting of iron polysaccharide, iron bisglycinate and iron proteinate, and combinations thereof.

According to a further aspect, there is provided a composition for treating iron deficiency anemia, consisting essentially of:

heme iron polypeptide; and,

iron polysaccharide.

According to another aspect there is provided a composition for treating iron deficiency anemia, consisting essentially of:

heme iron polypeptide; and,

a chelated iron selected from the group consisting of iron polysaccharide, iron bisglycinate, iron proteinate, and combinations thereof.

According to a further aspect, there is provided a

composition for treating iron deficiency anemia, consisting essentially of:

heme iron polypeptide;

an iron material selected from the group consisting of ionic irons, chelated irons selected from the group consisting of iron polysaccharide, iron bisglycinate and iron proteinate, and combinations thereof; and,

at least one vitamin selected from the group consisting of folic acid, vitamin B6, and vitamin B12.

According to another aspect, there is provided a composition for treating iron deficiency anemia, consisting essentially of:

heme iron polypeptide;

iron polysaccharide; and,

at least one vitamin selected from the group consisting of folic acid, vitamin B6, and vitamin B12.

According to a further aspect, there is provided a composition for treating iron deficiency anemia, consisting essentially of:

heme iron polypeptide;

a chelated iron selected from the group consisting of iron polysaccharide, iron bisglycinate, iron proteinate, and

combinations thereof; and,

at least one vitamin selected from the group consisting of folic acid, vitamin B6, and vitamin B12.

According to another aspect, there is provided a composition for human consumption consisting essentially of:

a first iron ingredient, wherein said first iron ingredient is heme iron polypeptide; and,

a second iron ingredient selected from the group consisting of ionic irons, chelated irons selected from the group consisting of iron polysaccharide, iron bisglycinate and iron proteinate, and combinations thereof.

According to a further aspect, there is provided a composition for human consumption consisting essentially of:

heme iron polypeptide;

an iron material selected from the group consisting of ionic irons, chelated irons selected from the group consisting of iron polysaccharide, iron bisglycinate and iron proteinate, and combinations thereof; and,

at least one nutrient selected from the group consisting of vitamins, minerals, and a combination thereof.

According to another aspect, there is provided a

composition for human consumption consisting essentially of:

heme iron polypeptide;

iron polysaccharide; and,

at least one nutrient selected from the group consisting of vitamins, minerals, and a combination thereof.

According to a further aspect, there is provided a composition for human consumption consisting essentially of:

heme iron polypeptide;

a chelated iron selected from the group consisting of iron polysaccharide, iron bisglycinate, iron proteinate, and combinations thereof; and,

at least one nutrient selected from the group consisting of vitamins, minerals, and a combination thereof.

According to another aspect there is provided an iron composition consisting essentially of:

heme iron polypeptide; and,

an iron material selected from the group consisting of ionic irons, chelated irons selected from the group consisting of iron polysaccharide, iron bisglycinate and iron proteinate, and combinations thereof,

wherein said iron composition is included within a dose

for human administration, and wherein said dose is formulated to further include at least one vitamin and at least one mineral.

According to a further aspect, there is provided an iron composition consisting essentially of:

heme iron polypeptide; and,

iron polysaccharide,

wherein said iron composition is included within a dose for human administration, and wherein said dose is formulated to further include at least one vitamin and at least one mineral.

According to another aspect, there is provided an iron composition consisting essentially of:

heme iron polypeptide; and,

a chelated iron selected from the group consisting of iron polysaccharide, iron bisglycinate, iron proteinate, and combinations thereof,

wherein said iron composition is included within a dose for human administration, and wherein said dose is formulated to further include at least one vitamin and at least one mineral.

According to a further aspect, there is provided a pharmaceutical composition for treating iron deficiency or iron deficiency anemia in a human, consisting essentially of:

heme iron polypeptide; and,

at least one chelated iron selected from the group consisting of iron polysaccharide, iron bisglycinate, iron proteinate, and combinations thereof,

wherein said pharmaceutical composition is formulated for oral administration, and is contained within a unit selected from the group consisting of a tablet and a capsule.

According to another aspect, there is provided a pharmaceutical composition for treating iron deficiency or iron deficiency anemia in a human, consisting essentially of:

heme iron polypeptide; and,

iron polysaccharide,

wherein said pharmaceutical composition is formulated for oral administration, and is contained within a unit selected from the group consisting of a tablet and a capsule.

According to a further aspect, there is provided a pharmaceutical composition for treating iron deficiency or iron deficiency anemia in a human, consisting essentially of:

heme iron polypeptide;

iron polysaccharide; and,

at least one vitamin selected from the group consisting of folic acid, vitamin B6, vitamin B12, and combinations thereof,

wherein said pharmaceutical composition is formulated for oral administration, and is contained within a unit selected from the group consisting of a tablet and a capsule.

According to another aspect, there is provided a pharmaceutical composition for treating iron deficiency or iron deficiency anemia in a human, consisting essentially of:

heme iron polypeptide;

at least one chelated iron selected from the group consisting of iron polysaccharide, iron bisglycinate, iron proteinate, and combinations thereof; and,

at least one vitamin selected from the group consisting of folic acid, vitamin B6, vitamin B12, and combinations

thereof,

wherein said pharmaceutical composition is formulated for oral administration, and is contained within a unit selected from the group consisting of a tablet and a capsule.

According to a further aspect, there is provided a pharmaceutical composition for nutritional supplementation in a prenatal or lactating human female, consisting essentially of:

heme iron polypeptide;

iron polysaccharide; and,

at least one nutrient selected from the group consisting of vitamins, minerals, and a combination thereof,

wherein said pharmaceutical composition is formulated for oral administration, and is contained within a unit selected from the group consisting of a tablet and a capsule.

According to another aspect, there is provided a pharmaceutical composition for nutritional supplementation in a prenatal or lactating human female, consisting essentially of:

heme iron polypeptide;

at least one chelated iron selected from the group consisting of iron polysaccharide, iron bisglycinate, iron proteinate, and combinations thereof; and,

at least one nutrient selected from the group consisting of vitamins, minerals, and a combination thereof,

wherein said pharmaceutical composition is formulated for oral administration, and is contained within a unit selected from the group consisting of a tablet and a capsule.

According to a further aspect, there is provided a pharmaceutical composition for nutritional supplementation in a prenatal or lactating human female, consisting essentially of:

heme iron polypeptide; and,

iron polysaccharide,

wherein said pharmaceutical composition is formulated for oral administration, and is contained within a capsule, said capsule further including additional nutrients for the prenatal or lactating human female.

According to another aspect, there is provided a

pharmaceutical composition for nutritional supplementation in a prenatal or lactating human female, consisting essentially of:

heme iron polypeptide; and,

at least one chelated iron selected from the group consisting of iron polysaccharide, iron bisglycinate, iron proteinate, and combinations thereof,

wherein said pharmaceutical composition is formulated for oral administration, and is contained within a capsule, said capsule further including additional nutrients for the prenatal or lactating human female.

Accordingly, a feature and advantage of the present invention is its ability to provide a composition comprising heme iron and/or heme iron polypeptide in combination with ionic iron(s) and/or chelated iron(s).

Another feature and advantage of the present invention is its ability to provide a composition comprising heme iron and/or heme iron polypeptide in combination with ionic iron(s) and/or chelated iron(s), in addition to various selected prenatal vitamins.

Still another feature and advantage of the present invention is its ability to provide a composition comprising heme iron and/or heme iron polypeptide in combination with ionic iron(s) and/or chelated iron(s), for the treatment and/or prevention of iron deficiency anemia.

Yet another feature and advantage of the present invention is its ability to provide a composition comprising heme iron and/or heme iron polypeptide in combination with ionic iron(s) and/or chelated iron(s), in addition to a various selected prenatal vitamins, for the treatment and/or prevention of iron deficiency anemia.

Still yet another feature and advantage of the present invention is its ability to provide a composition comprising

heme iron and/or heme iron polypeptide in combination with ionic iron(s) and/or chelated iron(s), as an effective vitamin supplement for pregnant and/or nursing females.

A further feature and advantage of the present invention is its ability to provide a composition comprising heme iron and/or heme iron polypeptide in combination with ionic iron(s) and/or chelated iron(s), in addition to a various selected vitamins, as an effective vitamin supplement for pregnant and/or nursing females.

Still a further feature and advantage of the present invention is its ability to provide methods for the treatment and/or prevention of iron deficiency anemia, by administering a composition comprising heme iron and/or heme iron polypeptide in combination with ionic iron(s) and/or chelated iron(s) and, selectively, various vitamins, prenatal or otherwise.

These and other features and advantages of the invention will become more apparent to one skilled in the art from the following description and claims when read in light of the accompanying drawings.

## DETAILED DESCRIPTION OF THE PREFERRED AND SELECTED ALTERNATIVE EMBODIMENTS

This Patent Cooperation Treaty application claims priority to and the benefit of United States Non-Provisional patent application entitled "Composition and Method for Treating Iron Deficiency Anemia," filed September 19, 2005, on behalf of inventors Bala Venkataraman and Michael Guthrie, having assigned Serial No. 11/230,042.

In describing the preferred and selected alternate embodiments of the present invention, specific terminology is employed for the sake of clarity. The invention, however, is not intended to be limited to the specific terminology so selected, and it is to be understood that each specific element includes all technical or compositional equivalents that operate or perform in a similar manner to accomplish similar functions.

The present invention is a composition and method for treating and/or preventing iron deficiency anemia.

Iron Compositions

The composition of the present invention preferably comprises heme iron in combination with ionic iron(s) and/or chelated iron(s). In another preferred embodiment of the present invention, the composition preferably comprises heme

iron polypeptide in combination with ionic iron(s) and/or chelated iron(s), wherein the heme iron polypeptide is preferably in the form of a proteolytic digest of bovine and/or porcine hemoglobin; however, it should be recognized that other derivations of heme iron polypeptide may be procured from the hemoglobin and/or myoglobin molecular complexes of alternate animal species. In still another preferred embodiment of the present invention, the composition preferably comprises heme iron and heme iron polypeptide in combination with ionic iron(s) and/or chelated iron(s). Indeed, the present invention contemplates numerous preferred embodiments of the instant composition, wherein the amounts of each specific ingredient, in any varying combination, may be appropriately selected based upon the treatment measures, protocols and/or other diagnostics relevant to the targeted patient populace. Accordingly, and as more fully described hereinbelow, the amounts and type of each specific ingredient, in any varying combination, are only exemplary preparations of the present composition and, thus, are not intended to so limit the multitude of combinations attainable from the present invention. It is also to be understood that as used in the specification and in the claims, "a" or "an" can mean one or more, depending upon the context in which it is used.

The ionic irons of the present composition are preferably in the form of soluble iron salts, but may further include,

without limitation, slightly soluble iron salts, insoluble iron salts, carbonyl irons, and blends, mixtures or combinations thereof. Accordingly, the selected soluble iron salt(s) may include, without limitation, ferrous sulfate, ferrous gluconate, ferrous fumarate, ferric hypophosphite, ferric albuminate, ferric chloride, ferric citrate, ferric oxide saccharated, ferric ammonium citrate, ferrous chloride, ferrous iodide, ferrous lactate, ferric trisglycinate, ferrous bisglycinate, ferric nitrate, ferrous hydroxide saccharate, ferric sulfate, ferric gluconate, ferric aspartate, ferrous sulfate heptahydrate, ferrous phosphate, ferric ascorbate, ferrous formate, ferrous acetate, ferrous malate, ferrous glutamate, ferrous cholinisocitrate, ferroglycine sulfate, ferric oxide hydrate, ferric pyrophosphate soluble, ferric hydroxide saccharate, ferric manganese saccharate, ferric subsulfate, ferric ammonium sulfate, ferrous ammonium sulfate, ferric sesquichloride, ferric choline citrate, ferric manganese citrate, ferric quinine citrate, ferric sodium citrate, ferric sodium edetate, ferric formate, ferric ammonium oxalate, ferric potassium oxalate, ferric sodium oxalate, ferric peptonate, ferric manganese peptonate, other pharmaceutically acceptable soluble iron salts, blends, mixtures and/or combinations thereof.

As an alternative to the selected soluble iron salt(s), or in conjunction therewith, a slightly soluble salt(s) may be

utilized in the present composition, wherein the slightly soluble salt(s) may include, without limitation, ferric acetate, ferric fluoride, ferric phosphate, ferric pyrophosphate, ferrous pyrophosphate, ferrous carbonate saccharated, ferrous carbonate mass, ferrous succinate, ferrous citrate, ferrous tartrate, ferric fumarate, ferric succinate, ferrous hydroxide, ferrous nitrate, ferrous carbonate, ferric sodium pyrophosphate, ferric tartrate, ferric potassium tartrate, ferric subcarbonate, ferric glycerophosphate, ferric saccharate, ferric hydroxide saccharate, ferric manganese saccharate, ferrous ammonium sulfate, other pharmaceutically acceptable slightly soluble iron salts, blends, mixtures and/or combinations thereof.

Additionally, as an alternative to the selected soluble iron salt(s) and/or slightly soluble salt(s), or in conjunction therewith, an insoluble salt(s) may be utilized in the present composition, wherein the insoluble salt(s) may include, without limitation, ferric sodium pyrophosphate, ferrous carbonate, ferric hydroxide, ferrous oxide, ferric oxyhydroxide, ferrous oxalate, other pharmaceutically acceptable insoluble iron salts, blends, mixtures and/or combinations thereof.

As described hereinabove, and as an alternative to any one or more of the foregoing enumerated iron salts, or in conjunction therewith, the present composition may selectively comprise a chelated iron in combination with the selected heme

iron and/or heme iron polypeptide. Accordingly, in such an embodiment, the chelated iron of the present composition may be selected from any one or more of the preferred complexes of iron polysaccharide, iron bis glycinate, and/or iron proteinate. However, alternate chelated iron complexes are contemplated and, as such, may include, without limitation, methylidine-iron complex, EDTA-iron complex, phenanthrolene iron complex, p-toluidine iron complex, ferrous saccharate complex, ferrlecit, ferrous gluconate complex, ferrum vitis, ferrous hydroxide saccharate complex, iron-arene sandwich complexes, acetylacetone iron complex salt, iron-dextran complex, iron-dextrin complex, iron-sorbitol-citric acid complex, saccharated iron oxide, ferrous fumarate complex, iron porphyrin complex, iron phtalocyamine complex, iron cyclam complex, dithiocarboxy-iron complex, desferrioxamine-iron complex, bleomycin-iron complex, ferrozine-iron complex, iron perhaloporphyrin complex, alkylenediamine-N,N'-disuccinic acid iron(III) complex, hydroxypyridone-iron(III) complex, aminoglycoside-iron complex, transferrin-iron complex, iron thiocyanate complex, iron complex cyanides, porphyrinato iron(III) complex, polyaminopolycarbonate iron complexes, dithiocarbamate iron complex, adriamycin iron complex, anthracycline-iron complex, MGD-iron complex, ferrioxamine B, ferrous citrate complex, ferrous sulfate complex, ferric gluconate complex, ferrous succinate complex, polyglucopyranosyl iron complex, polyaminodisuccinic acid iron complex, biliverdin-iron complex, deferiprone iron complex,

ferric oxyhydride-dextran complex, dinitrosyl dithiolato iron complex, iron lactoferrin complexes, 1,3-PDTA ferric complex salts, diethylenetriaminepentaacetic acid iron complex salts, cyclohexanediaminetetraacetic acid iron complex salts, methyliminodiacetic acid iron complex salts, glycol ether diaminetetraacetic acid iron complex salts, ferric hydroxypyrone complexes, ferric succinate complex, ferric chloride complex, ferric glycine sulfate complex, ferric aspartate complex, sodium ferrous gluconate complex, ferrous hydroxide polymaltose complex, other pharmaceutically acceptable chelated iron complexes, blends, mixtures and/or combinations thereof.

Still, in certain embodiments, the present composition may further selectively comprise vitamins and minerals, including, without limitation, folic acid, vitamin A, vitamin B (all series, including B3, B6, B12), vitamin C, vitamin D, vitamin E, calcium, magnesium, or the like, so as to provide a prenatal composition. Accordingly, as used herein, the term "vitamin B3" refers to niacin and nicotinic acid. As also used herein, the term "vitamin B6" refers to pyridoxal, pyridoxamine and pyridoxine compounds. The term "vitamin B12" refers to all forms of cobalamin including, without limitation, hydroxocobalamin, cyanocobalamin and methylcobalamin. The term "vitamin C" is used herein to refer to any form of vitamin C, including ascorbate and L threonate. The term "vitamin D" is used to refer to both cholecalciferol (vitamin D3) and

ergocalciferol (vitamin D2). The term "vitamin E" is used herein to refer to alpha-tocopherol, d-alpha-tocopherol, d-alpha-tocopheryl succinate (or acetate), dl-alpha-tocopherol, dl-alpha-tocopheryl acetate (or succinate), gamma tocopherol, mixed tocopherols, and dl-alpha tocopherol nicotinate. The term "calcium" is used herein to refer to any form of calcium including calcium carbonate, phosphate, lactate, gluconate, citrate and combinations thereof. The term "magnesium" is used herein to refer to any form of magnesium, including magnesium oxide, magnesium chloride, magnesium lactate, magnesium sulfate and magnesium gluconate. As such, the various compositions of the present invention may include one or more forms of the foregoing vitamins and/or minerals in any amount and in any combination with the selected heme iron and/or heme iron polypeptide, and the selected iron salt(s) and/or chelated iron(s).

Turning now to one of the many preferred embodiments of the present invention, a preferred composition preferably comprises any combination of the following amounts of the specific ingredients *(nota bene: all of the following amounts of iron are in terms of total elemental iron)*: heme iron or heme iron polypeptide, or a combination thereof, in an amount between about 2mg and about 12mg, and preferably between about 6mg and about 9mg; and, ionic iron(s) or chelated iron(s), or a combination thereof, in an amount between about 15mg and about

100mg, and preferably between about 20mg and about 75mg. The instant composition may further specifically comprise folic acid in an amount between about 0.1mg and about 5mg, and preferably between about 0.4mg and about 2mg; and/or, vitamin B12 in an amount between about 1mcg and about 900mcg, and preferably between about 12mcg and about 500mcg.

In another preferred embodiment of the present invention, the composition comprises one of heme iron, heme iron polypeptide, ionic iron(s) and chelated iron(s) in the ranges prescribed hereinabove, and the remaining selected ingredients in any amount. For example, the composition may comprises heme iron in an amount between about 2mg and about 12mg, and preferably between about 6mg and about 9mg (total elemental iron); and, ionic iron(s) or chelated iron(s), or a combination thereof, in any amount. Another composition may similarly comprise heme iron polypeptide in an amount between about 2mg and about 12mg, and preferably between about 6mg and about 9mg (total elemental iron); and, ionic iron(s) or chelated iron(s), or a combination thereof, in any amount. Another composition may comprise heme iron and heme iron polypeptide in a combined amount between about 2mg and about 12mg, and preferably between about 6mg and about 9mg (total elemental iron); and, ionic iron(s) or chelated iron(s), or a combination thereof, in any amount. Another composition may comprise ionic iron(s) in an amount between about 15mg and about 100mg, and preferably

between about 20mg and about 75mg (total elemental iron); and, heme iron or heme iron polypeptide, or a combination thereof, in any amount. Another composition may comprise chelated iron(s) in an amount between about 15mg and about 100mg, and preferably between about 20mg and about 75mg (total elemental iron); and, heme iron or heme iron polypeptide, or a combination thereof, in any amount. Another composition may comprise ionic iron(s) and chelated iron(s) in a combined amount between about 15mg and about 100mg, and preferably between about 20mg and about 75mg (total elemental iron); and, heme iron or heme iron polypeptide, or a combination thereof, in any amount. Additionally, the foregoing compositions may further selectively comprise any one or more of the foregoing vitamins and minerals, including folic acid and/or vitamin B12 within the limits prescribed hereinabove, or in any amount.

In still another preferred embodiment of the present invention, the composition comprises heme iron or heme iron polypeptide, or a combination thereof, in an amount of about 6mg (total elemental iron); and, ionic iron(s) or chelated iron(s), or a combination thereof, in an amount of about 21mg (total elemental iron), wherein the instant composition may further selectively comprise any one or more of the foregoing vitamins and minerals, including folic acid and/or vitamin B12 within the limits prescribed hereinabove. A preferred variation of the instant embodiment comprises heme iron or heme iron polypeptide,

or a combination thereof, in an amount of about 6mg (total elemental iron); and, ionic iron(s) or chelated iron(s), or a combination thereof, in any amount. Another preferred variation of the instant embodiment comprises ionic iron(s) or chelated iron(s), or a combination thereof, in an amount of about 21mg (total elemental iron); and, heme iron or heme iron polypeptide, or a combination thereof, in any amount.

In still yet another preferred embodiment of the present invention, the composition comprises heme iron or heme iron polypeptide, or a combination thereof, in an amount of about 12mg (total elemental iron); and, ionic iron(s) or chelated iron(s), or a combination thereof, in an amount of about 15mg (total elemental iron), wherein the instant composition may further selectively comprise any one or more of the foregoing vitamins and minerals, including folic acid and/or vitamin B12 within the limits prescribed hereinabove. A preferred variation of the instant embodiment comprises heme iron or heme iron polypeptide, or a combination thereof, in an amount of about 12mg (total elemental iron); and, ionic iron(s) or chelated iron(s), or a combination thereof, in any amount. Another preferred variation of the instant embodiment comprises ionic iron(s) or chelated iron(s), or a combination thereof, in an amount of about 15mg (total elemental iron); and, heme iron or heme iron polypeptide, or a combination thereof, in any amount.

In a further preferred embodiment of the present invention, the composition comprises heme iron or heme iron polypeptide, or a combination thereof, in an amount of about 12mg (total elemental iron); and, ionic iron(s) or chelated iron(s), or a combination thereof, in an amount of about 63mg (total elemental iron), wherein the instant composition may further selectively comprise any one or more of the foregoing vitamins and minerals, including folic acid and/or vitamin B12 within the limits prescribed hereinabove. A preferred variation of the instant embodiment comprises heme iron or heme iron polypeptide, or a combination thereof, in an amount of about 12mg (total elemental iron); and, ionic iron(s) or chelated iron(s), or a combination thereof, in any amount. Another preferred variation of the instant embodiment comprises ionic iron(s) or chelated iron(s), or a combination thereof, in an amount of about 63mg (total elemental iron); and, heme iron or heme iron polypeptide, or a combination thereof, in any amount.

In other embodiments of the present invention, various compositions may comprise heme iron and/or heme iron polypeptide in combination with ionic iron(s) and/or chelated iron(s), each in any amount, within the prescribed limits described hereinabove, or otherwise selected for effective treatment and/or prevention of iron deficiency anemia, as more fully described hereinbelow.

Auxiliary Agents

The iron compositions of the present invention may be a part of a formulation that also contains at least one of any suitable auxiliary agents such as, but not limited to, diluents, binders, stabilizers, buffers, salts, lipophilic solvents, preservatives, or the like. Pharmaceutically acceptable auxiliaries are preferred. Examples and methods of preparing such sterile solutions are well known in the art and can be found in well-known literature such as, but not limited to, REMINGTON'S PHARMACEUTICAL SCIENCES (Gennaro, Ed., 18th Edition, Mack Publishing Co. (1990)). Pharmaceutically acceptable carriers can be routinely selected that are suitable for the mode of administration, solubility and/or stability of the compound.

Pharmaceutical excipients and additives useful in the present invention include, but are not limited to, proteins, peptides, amino acids, lipids, and carbohydrates (e.g., sugars, including monosaccharides, di-, tri-, tetra-, and oligosaccharides; derivatized sugars such as alditols, aldonic acids, esterified sugars and the like; and polysaccharides or sugar polymers), which can be present singly or in combination, comprising alone or in combination in ranges of 1-99.99% by weight or volume. Exemplary protein excipients include serum albumin such as human serum albumin (HSA), recombinant human albumin (rHA), gelatin, casein, and the like. Representative

amino acid components, which can also function in a buffering capacity, include alanine, glycine, arginine, betaine, histidine, glutamic acid, aspartic acid, cysteine, lysine, leucine, isoleucine, valine, methionine, phenylalanine, aspartame, and the like.

Carbohydrate excipients suitable for use in the present invention include, for example, monosaccharides such as fructose, maltose, galactose, glucose, D-mannose, sorbose, and the like; disaccharides, such as lactose, sucrose, trehalose, cellobiose, and the like; polysaccharides, such as raffinose, melezitose, maltodextrins, dextrans, starches, and the like; and alditols, such as mannitol, xylitol, maltitol, lactitol, sorbitol (glucitol), myoinositol and the like.

The compositions of the present invention can also be a part of a formulation that includes a buffer or a pH-adjusting agent. Typically, the buffer is a salt prepared from an organic acid or base. Representative buffers include organic acid salts such as salts of citric acid, ascorbic acid, gluconic acid, carbonic acid, tartaric acid, succinic acid, acetic acid, or phthalic acid; Tris, tromethamine hydrochloride, or phosphate buffers.

Additionally, compositions of the invention can be a part of a formulation that includes polymeric excipients/additives

such as polyvinylpyrrolidones, ficolls (a polymeric sugar), dextrates (e.g., cyclodextrins, such as 2-hydroxypropyl-β-cyclodextrin), polyethylene glycols, flavoring agents, antimicrobial agents, sweeteners, antioxidants, anti-static agents, surfactants (e.g., polysorbates such as "TWEEN™ 20" and "TWEEN™ 80"), lipids (e.g., phospholipids, fatty acids), steroids (e.g., cholesterol), and chelating agents (e.g., EDTA). These and additional known pharmaceutical excipients and/or additives suitable for use in the present invention are known in the art, e.g., as listed in REMINGTON: THE SCIENCE & PRACTICE OF PHARMACY (19th ed., Williams & Williams (1995)) and PHYSICIAN'S DESK REFERENCE (52nd ed., Medical Economics (1998)).

Formulations for Oral Administration

For oral administration in the form of a tablet or capsule, the various compositions described herein may be combined with an oral, non-toxic pharmaceutically acceptable inert carrier such as ethanol, glycerol, water and the like to create the formulation. Moreover, when desired or necessary, suitable binders, lubricants, disintegrating agents, flavoring and coloring agents may also be incorporated into the mixture. Suitable binders include, without limitation, starch; gelatin; natural sugars such as glucose or beta-lactose; corn sweeteners; natural and synthetic gums such as acacia, tragacanth, or sodium alginate, carboxymethylcellulose; polyethylene glycol; waxes and

the like. Lubricants used in these dosage forms include, without limitation, sodium oleate, sodium stearate, calcium stearate, sodium benzoate, sodium acetate, sodium chloride and the like. Disintegrators include, without limitation, starch, methyl cellulose, agar, bentonite, xanthan gum and the like. In one embodiment, a composition or formulation suitable for oral administration could comprise carnauba wax, citric acid, dicalcium phosphate, hydroxypropyl methylcellulose, calcium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, riboflavin, silicon dioxide, sodium benzoate, sodium citrate, sodium starch glycolate, sorbic acid, starch, stearic acid and titanium dioxide.

Compositions or formulations of the present invention suitable for oral administration may be presented as discrete units such as capsules, cachets or tablets each containing a predetermined amount of a ingredient; as a powder or granules; as a solution or a suspension in an aqueous liquid or a non-aqueous liquid; or as an oil-in-water liquid emulsion or a water-in-oil emulsion and as a bolus, etc. In a preferred embodiment, the composition or formulation is in the form of a tablet.

A tablet may be made by compression or molding, optionally with one or more accessory ingredients. Compressed tablets may be prepared by compressing, in a suitable machine, the active

ingredient in a free-flowing form such as a powder or granules, optionally mixed with a binder, lubricant, inert diluent, preservative, surface active or dispersing agent. Molded tablets may be made by molding, in a suitable machine, a mixture of the powdered compound moistened with an inert liquid diluent. The tablets may be optionally coated or scored and may be formulated so as to provide a slow or controlled release of the ingredient(s) therein.

Preferred unit dosage formulations are those containing a daily dose or unit, daily sub-dose, or an appropriate fraction thereof, of the administered ingredient. In a more preferred embodiment, the unit dosage formulation contains from one daily dose or half of a daily dose of the compositions described hereinabove.

## EXAMPLE

*Preparation of Composition for Oral Administration:*

A composition of the present invention was prepared that comprises weighed amounts of heme iron polypeptide, iron polysaccharide, folic acid, hydroxocobalamin, calcium silicate synthetic (Micro Cel), microcrystalline cellulose PH-200, silicon dioxide FG, modified cellulose gum (Ac-Di-Sol), and magnesium stearate NF.

All ingredients were filtered through a #20 mesh screen. Heme iron polypeptide and iron polysaccharide were pre-blended in an LV blender with calcium silicate synthetic for 10 minutes. If the blend was lumpy, it was passed through a #20 mesh screen.

Folic acid, hydroxocobalamin, a selected amount of microcrystalline cellulose, and the foregoing pre-blend were loaded into an XLV blender and blended for 15 minutes. Thereafter, silicon dioxide FG, modified cellulose gum, and the remainder of microcrystalline cellulose were loaded into the XLV blender, and all materials were blended for an additional 10 minutes. Magnesium stearate was then added, and all materials were blended for an additional 5 minutes.

Following completion of the blend process, the blend was discharged and compressed into tablets according to selected specifications. The finished tablets were coated in an Accela Cota, utilizing dispersed OPADRY white with purified water as the coating solution.

Formulations for Other Routes of Administration

Formulations suitable for parenteral administration include aqueous and non-aqueous sterile injection solutions which may contain anti-oxidants, buffers, bacteriostats and solutes that render the formulation isotonic with the blood of the intended

recipient; and aqueous and non-aqueous sterile suspensions which may include suspending agents and thickening agents. The formulations may be presented in unit-dose or multi-dose containers, for example, sealed ampules and vials, and may be stored in a freeze-dried (lyophilized) condition requiring only the addition of the sterile liquid carrier, for example, water for injections, immediately prior to use. Extemporaneous injection solutions and suspensions may be prepared from sterile powders, granules and tablets of the kind previously described.

For parenteral administration, sterile suspensions and solutions are desired. Isotonic preparations, which generally contain suitable preservatives, are employed when intravenous administration is desired. The compositions may be administered parenterally via injection of a formulation consisting of the active ingredients dissolved in an inert liquid carrier. The term "parenteral," as used herein, includes, but is not limited to, subcutaneous injections, intravenous, intramuscular, intraperitoneal injections, or infusion techniques. Acceptable liquid carriers include, for example, vegetable oils such as peanut oil, cottonseed oil, sesame oil and the like, as well as organic solvents such as solketal, glycerol formal and the like. Dissolving or suspending the composition in the liquid carrier such that the final formulation contains from about 0.005% to about 30% by weight of the active ingredient, i.e., a composition of the present invention.

Formulations suitable for topical administration in the mouth include lozenges comprising the ingredients in a flavored basis, usually sucrose and acacia or tragacanth; pastilles comprising the composition in an inert basis such as gelatin and glycerin, or sucrose and acacia; and mouthwashes comprising the composition to be administered in a suitable liquid carrier. The liquid forms may include suitably flavored suspending or dispersing agents such as the synthetic and natural gums, for example, tragacanth, acacia, methyl-cellulose and the like.

Formulations suitable for nasal administration, wherein the carrier is a solid, include a coarse powder having a particle size, for example, in the range of 20 to 500 microns which is administered in the manner in which snuff is taken, i.e., by rapid inhalation through the nasal passage from a container of the powder held close up to the nose. Suitable formulations, wherein the carrier is a liquid, for administration, as for example, a nasal spray or as nasal drops, include aqueous or oily solutions of the composition.

The compositions may also be entrapped in microcapsules prepared, for example, by coacervation techniques or by interfacial polymerization, for example, hydroxymethylcellulose or gelatin-microcapsules and poly(methylmethacylate) microcapsules, respectively, in colloidal drug delivery systems

(for example, liposomes, albumin microspheres, microemulsions, nano-particles and nanocapsules) or in macroemulsions. REMINGTON'S PHARMACEUTICAL SCIENCES (A. Osol ed., 16th ed. (1980)).

In addition, the compositions may be incorporated into biodegradable polymers allowing for sustained release of the compound, the polymers being implanted in the vicinity of where delivery of the composition is desired, for example, within the buccal cavity. The biodegradable polymers and their uses are described, for example, in detail in Brem et al., 74 J. NEUROSURG. 441-46 (1991). Suitable examples of sustained-release compositions include semipermeable matrices of solid hydrophobic polymers containing a composition of the present invention, which matrices are in the form of shaped articles, e.g., films, or microcapsules. Examples of sustained-release matrices include polyesters, hydrogels (for example, poly(2-hydroxyethyl-methacrylate), or poly(vinylalcohol)), polylactides (U.S. Patent No. 3,773,919), copolymers of L-glutamic acid and y ethyl-L-glutamate, non-degradable ethylene-vinyl acetate, degradable lactic acid-glycolic acid copolymers such as the LUPRON DEPOT® (Tap Pharmaceuticals, Inc., Chicago, IL) (injectable microspheres composed of lactic acid glycolic acid copolymer and leuprolide acetate), and poly-D-(-)-3-hydroxybutyric acid.

Pharmaceutically Acceptable Preservatives

The present invention provides stable compositions as well as preserved solutions and formulations containing a preservative as well as multi-use preserved formulations suitable for pharmaceutical or veterinary use, comprising a composition disclosed herein in a pharmaceutically acceptable formulation. Formulations in accordance with the present invention may optionally contain at least one known preservative. Preservatives include, but are not limited to, phenol, m-cresol, p-cresol, o-cresol, chlorocresol, benzyl alcohol, phenylmercuric nitrite, phenoxyethanol, formaldehyde, chlorobutanol, calcium chloride (e.g., hexahydrate), alkylparaben (methyl, ethyl, propyl, butyl and the like), benzalkonium chloride, benzethonium chloride, sodium dehydroacetate and thimerosal, or mixtures thereof in an aqueous diluent. Any suitable concentration or mixture can be used as known in the art, such as 0.001-5%, or any range or value therein. Non-limiting examples include, no preservative, 0.1-2% m-cresol, 0.1-3% benzyl alcohol, 0.001-0.5% thimerosal, 0.001-2.0% pheno, 0.0005-1.0% alkylparaben(s), and the like.

Other excipients, e.g., isotonicity agents, buffers, antioxidants, preservative enhancers, can be optionally added to the diluent. An isotonicity agent such as glycerin is commonly used at known concentrations. A physiologically tolerated

buffer is preferably added to provide improved pH control. The formulations can cover a wide range of pHs, such as from about pH 4.0 to about pH 10.0, specifically, a range from about pH 5.0 to about pH 9.0, and more specifically, a range of about 6.0 to about 8.0. Suitable buffers include phosphate buffers, for example, sodium phosphate and phosphate buffered saline (PBS).

Method for Treating Iron Deficiency

As described hereinabove, compositions of the present invention may comprise heme iron and/or heme iron polypeptide in combination with ionic iron(s) and/or chelated iron(s), each in any amount, within the prescribed limits described hereinabove, or otherwise selected for effective treatment and/or prevention of iron deficiency anemia. As such, via administration of effective dosages of the present composition, the instant invention further includes methods for treating and/or preventing iron deficiency anemia, and the physiological, biochemical, morphological, and behavioral manifestations symptomatic of same. Furthermore, inclusion of the foregoing prenatal vitamins within the present composition further provides an effective vitamin supplement for pregnant females, wherein other measured compositions may further be utilized for nursing mothers during periods of increased iron demand (i.e., lactational periods). Still other compositions may be prepared specifically for administration to children.

As used herein, the term "treatment of" or "treating" a condition does not require elimination of the condition, i.e., curing of a disease. Therefore, an "effective amount" or "effective dosage" of the present composition is defined herein as an amount of the composition capable of preventing or reducing the occurrence or severity of iron deficiency anemia, and/or the physiological, biochemical, morphological, and behavioral manifestations symptomatic of same.

Accordingly, implementation of the present method preferably comprises administration of a composition comprising any combination of the following amounts of the specific ingredients ("mg" amount representative of total elemental iron): heme iron or heme iron polypeptide, or a combination thereof, in an amount between about 2mg and about 12mg, and preferably between about 6mg and about 9mg; and, ionic iron(s) or chelated iron(s), or a combination thereof, in an amount between about 15mg and about 100mg, and preferably between about 20mg and about 75mg. The composition may further specifically comprise folic acid in an amount between about 0.1mg and about 5mg, and preferably between about 0.4mg and about 2mg; and/or, vitamin B12 in an amount between about 1mcg and about 900mcg, and preferably between about 12mcg and about 500mcg.

Although the present invention contemplates treatment and/or prevention of iron deficiency anemia, it should be

recognized that the present composition and method may be utilized to treat and/or prevent other forms or manifestations of iron deficiency, wherein methods of treatment of such alternate and additional manifestations may include administering a composition according any of the foregoing descriptions, or, alternatively, compositions comprising any of the afore-described ingredients in any selected combination.

Routes of Administration

When treating a condition associated with iron deficiency, the compositions disclosed herein may be administered to an individual by any of the following routes: oral, parenteral, subcutaneous, intramuscular, intravenous, intrarticular, intrabronchial, intraabdominal, intracapsular, intracartilaginous, intracavitary, intracelial, intracerebellar, intracerebroventricular, intracolic, intracervical, intragastric, intrahepatic, intramyocardial, intraosteal, intrapelvic, intrapericardiac, intraperitoneal, intrapleural, intraprostatic, intrapulmonary, intrarectal, intrarenal, intraretinal, intraspinal, intrasynovial, intrathoracic, intrauterine, intravesical, bolus, vaginal, rectal, buccal, sublingual, intranasal, iontophoretic means, and transdermal means. In a preferred embodiment, the present compositions are administered orally.

Having thus described the preferred and selected alternate embodiments of the present invention, it should be noted by those skilled in the art that the within disclosures are exemplary only, and that various other alternatives, adaptations, and modifications may be made within the scope of the present invention. Accordingly, the present invention is not limited to the specific embodiments illustrated herein, but is limited only by the following claims.

**WHAT IS CLAIMED IS:**

1. A composition for treating iron deficiency anemia, consisting essentially of:

heme iron polypeptide; and,

an iron material selected from the group consisting of ionic irons, chelated irons selected from the group consisting of iron polysaccharide, iron bisglycinate and iron proteinate, and combinations thereof.

2. The composition of claim 1, wherein said heme iron polypeptide is present in an amount between about 2 mg and about 12 mg of elemental iron.

3. The composition of claim 1, wherein said heme iron polypeptide is present in an amount between about 6 mg and about 9 mg of elemental iron.

4. The composition of claim 1, wherein said iron material is present in an amount between about 15 mg and about 100 mg of elemental iron.

5. The composition of claim 1, wherein said iron material is present in an amount between about 20 mg and about 75 mg

of elemental iron.

6. The composition of claim 1, wherein said heme iron polypeptide is present in an amount of about 6 mg of elemental iron, and wherein said iron material is present in an amount of about 21 mg of elemental iron.

7. The composition of claim 1, wherein said heme iron polypeptide is present in an amount of about 12 mg of elemental iron, and wherein said iron material is present in an amount of about 15 mg of elemental iron.

8. The composition of claim 1, wherein said heme iron polypeptide is present in an amount of about 12 mg of elemental iron, and wherein said iron material is present in an amount of about 63 mg of elemental iron.

9. The composition of claim 1, further comprising folic acid in an amount between about 0.1 mg and about 5 mg.

10. The composition of claim 1, further comprising folic acid in an amount between about 0.4 mg and about 2 mg.

11. The composition of claim 1, further comprising vitamin

B12 in an amount between about 1 mcg and about 900 mcg.

12. The composition of claim 1, further comprising vitamin B12 in an amount between about 12 mcg and about 500 mcg.

13. The composition of claim 1, further comprising at least one of folic acid, vitamin A, vitamin B (all series), vitamin C, vitamin D, vitamin E, calcium, and magnesium.

14. A composition for treating iron deficiency anemia, consisting essentially of:

heme iron polypeptide; and,

iron polysaccharide.

15. The composition of claim 14, wherein said heme iron polypeptide is present in an amount between about 2 mg and about 12 mg of elemental iron.

16. The composition of claim 14, wherein said heme iron polypeptide is present in an amount between about 6 mg and about 9 mg of elemental iron.

17. The composition of claim 14, wherein said iron polysaccharide is present in an amount between about 15 mg

and about 100 mg of elemental iron.

18. The composition of claim 14, wherein said iron polysaccharide is present in an amount between about 20 mg and about 75 mg of elemental iron.

19. The composition of claim 14, wherein said heme iron polypeptide is present in an amount of about 6 mg of elemental iron, and wherein said iron polysaccharide is present in an amount of about 21 mg of elemental iron.

20. The composition of claim 14, wherein said heme iron polypeptide is present in an amount of about 12 mg of elemental iron, and wherein said iron polysaccharide is present in an amount of about 15 mg of elemental iron.

21. The composition of claim 14, wherein said heme iron polypeptide is present in an amount of about 12 mg of elemental iron, and wherein said iron polysaccharide is present in an amount of about 63 mg of elemental iron.

22. A composition for treating iron deficiency anemia, consisting essentially of:

heme iron polypeptide; and,

a chelated iron selected from the group consisting of iron polysaccharide, iron bisglycinate, iron proteinate, and combinations thereof.

23. The composition of claim 22, wherein said heme iron polypeptide is present in an amount between about 2 mg and about 12 mg of elemental iron.

24. The composition of claim 22, wherein said heme iron polypeptide is present in an amount between about 6 mg and about 9 mg of elemental iron.

25. The composition of claim 22, wherein said chelated iron is present in an amount between about 15 mg and about 100 mg of elemental iron.

26. The composition of claim 22, wherein said chelated iron is present in an amount between about 20 mg and about 75 mg of elemental iron.

27. The composition of claim 22, wherein said heme iron polypeptide is present in an amount of about 6 mg of elemental iron, and wherein said chelated iron is present in an amount of about 21 mg of elemental iron.

28. The composition of claim 22, wherein said heme iron polypeptide is present in an amount of about 12 mg of elemental iron, and wherein said chelated iron is present in an amount of about 15 mg of elemental iron.

29. The composition of claim 22, wherein said heme iron polypeptide is present in an amount of about 12 mg of elemental iron, and wherein said chelated iron is present in an amount of about 63 mg of elemental iron.

30. A composition for treating iron deficiency anemia, consisting essentially of:

heme iron polypeptide;

an iron material selected from the group consisting of ionic irons, chelated irons selected from the group consisting of iron polysaccharide, iron bisglycinate and iron proteinate, and combinations thereof; and,

at least one vitamin selected from the group consisting of folic acid, vitamin B6, and vitamin B12.

31. A composition for treating iron deficiency anemia, consisting essentially of:

heme iron polypeptide;

iron polysaccharide; and,

at least one vitamin selected from the group consisting of folic acid, vitamin B6, and vitamin B12.

32. A composition for treating iron deficiency anemia, consisting essentially of:

heme iron polypeptide;

a chelated iron selected from the group consisting of iron polysaccharide, iron bisglycinate, iron proteinate, and combinations thereof; and,

at least one vitamin selected from the group consisting of folic acid, vitamin B6, and vitamin B12.

33. A composition for human consumption consisting essentially of:

a first iron ingredient, wherein said first iron ingredient is heme iron polypeptide; and,

a second iron ingredient selected from the group consisting of ionic irons, chelated irons selected from the group consisting of iron polysaccharide, iron bisglycinate and iron proteinate, and combinations thereof.

34. A composition for human consumption consisting essentially of:

heme iron polypeptide;

an iron material selected from the group consisting of ionic irons, chelated irons selected from the group consisting of iron polysaccharide, iron bisglycinate and iron proteinate, and combinations thereof; and,

at least one nutrient selected from the group consisting of vitamins, minerals, and a combination thereof.

35. A composition for human consumption consisting essentially of:

heme iron polypeptide;

iron polysaccharide; and,

at least one nutrient selected from the group consisting of vitamins, minerals, and a combination thereof.

36. A composition for human consumption consisting essentially of:

heme iron polypeptide;

a chelated iron selected from the group consisting of iron polysaccharide, iron bisglycinate, iron proteinate, and combinations thereof; and,

at least one nutrient selected from the group consisting of vitamins, minerals, and a combination thereof.

37. An iron composition consisting essentially of:

heme iron polypeptide; and,

an iron material selected from the group consisting of ionic irons, chelated irons selected from the group consisting of iron polysaccharide, iron bisglycinate and iron proteinate, and combinations thereof,

wherein said iron composition is included within a dose for human administration, and wherein said dose is formulated to further include at least one vitamin and at least one mineral.

38. An iron composition consisting essentially of:

heme iron polypeptide; and,

iron polysaccharide,

wherein said iron composition is included within a dose for human administration, and wherein said dose is formulated to further include at least one vitamin and at least one mineral.

39. An iron composition consisting essentially of:

heme iron polypeptide; and,

a chelated iron selected from the group consisting of iron polysaccharide, iron bisglycinate, iron proteinate, and combinations thereof,

wherein said iron composition is included within a dose for human administration, and wherein said dose is formulated to further include at least one vitamin and at least one mineral.

40. A pharmaceutical composition for treating iron deficiency or iron deficiency anemia in a human, consisting essentially of:

heme iron polypeptide; and,

at least one chelated iron selected from the group consisting of iron polysaccharide, iron bisglycinate, iron proteinate, and combinations thereof,

wherein said pharmaceutical composition is formulated for oral administration, and is contained within a unit selected from the group consisting of a tablet and a capsule.

41. A pharmaceutical composition for treating iron deficiency or iron deficiency anemia in a human, consisting essentially of:

heme iron polypeptide; and,

iron polysaccharide,

wherein said pharmaceutical composition is formulated for oral administration, and is contained within a unit

selected from the group consisting of a tablet and a capsule.

42. A pharmaceutical composition for treating iron deficiency or iron deficiency anemia in a human, consisting essentially of:

heme iron polypeptide;

iron polysaccharide; and,

at least one vitamin selected from the group consisting of folic acid, vitamin B6, vitamin B12, and combinations thereof,

wherein said pharmaceutical composition is formulated for oral administration, and is contained within a unit selected from the group consisting of a tablet and a capsule.

43. A pharmaceutical composition for treating iron deficiency or iron deficiency anemia in a human, consisting essentially of:

heme iron polypeptide;

at least one chelated iron selected from the group consisting of iron polysaccharide, iron bisglycinate, iron proteinate, and combinations thereof; and,

at least one vitamin selected from the group consisting

of folic acid, vitamin B6, vitamin B12, and combinations thereof,

wherein said pharmaceutical composition is formulated for oral administration, and is contained within a unit selected from the group consisting of a tablet and a capsule.

44. A pharmaceutical composition for nutritional supplementation in a prenatal or lactating human female, consisting essentially of:

heme iron polypeptide;

iron polysaccharide; and,

at least one nutrient selected from the group consisting of vitamins, minerals, and a combination thereof,

wherein said pharmaceutical composition is formulated for oral administration, and is contained within a unit selected from the group consisting of a tablet and a capsule.

45. A pharmaceutical composition for nutritional supplementation in a prenatal or lactating human female, consisting essentially of:

heme iron polypeptide;

at least one chelated iron selected from the group

consisting of iron polysaccharide, iron bisglycinate, iron proteinate, and combinations thereof; and,

at least one nutrient selected from the group consisting of vitamins, minerals, and a combination thereof,

wherein said pharmaceutical composition is formulated for oral administration, and is contained within a unit selected from the group consisting of a tablet and a capsule.

46. A pharmaceutical composition for nutritional supplementation in a prenatal or lactating human female, consisting essentially of:

heme iron polypeptide; and,

iron polysaccharide,

wherein said pharmaceutical composition is formulated for oral administration, and is contained within a capsule, said capsule further including additional nutrients for the prenatal or lactating human female.

47. A pharmaceutical composition for nutritional supplementation in a prenatal or lactating human female, consisting essentially of:

heme iron polypeptide; and,

at least one chelated iron selected from the group consisting of iron polysaccharide, iron bisglycinate, iron proteinate, and combinations thereof,

wherein said pharmaceutical composition is formulated for oral administration, and is contained within a capsule, said capsule further including additional nutrients for the prenatal or lactating human female.