IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: **14/100,717**	Examiner: **LAU, JONATHAN S**
Applicant: **HELENEK, MARY JANE**	Group Art Unit: **1673**
Filed: **09 December 2013**	Confirmation No.: **2813**
Title: **METHODS AND COMPOSITIONS FOR ADMINISTRATION OF IRON**	Customer No.: **26263**
Docket No.: **30015730-0065**	

09 June 2014

FILED ELECTRONICALLY VIA EFS-WEB

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE TO OFFICE ACTION

UNDER 37 C.F.R. § 1.111

Sir:

In response to the Office Action of 07 February 2014, Applicants request the Office to enter the following amendments and consider the remarks set forth below.

Because 07 June 2014, falls on a weekend, this Response is being filed on the next following business day, 09 June 2014, and is, therefore, timely filed as of the four month date.

IN THE CLAIMS

1. (currently amended) A method of treating a disease, disorder, or condition characterized by iron deficiency or dysfunctional iron metabolism resulting in reduced bioavailability of dietary iron, comprising

administering to a subject in need thereof an iron carbohydrate complex in a single dosage unit of at least about 0.6 grams of elemental iron;

wherein

the iron carbohydrate complex is selected from the group consisting of an iron carboxymaltose complex, an iron mannitol complex, an iron polyisomaltose complex, an iron polymaltose complex, ~~an iron gluconate complex,~~ an iron sorbitol complex, an iron polyglucose sorbitol carboxymethyl ether complex, and an iron hydrogenated dextran complex;

the single dosage unit of elemental iron is administered in about 15 minutes or less; and

the iron carbohydrate complex has a substantially non-immunogenic carbohydrate component.

2. (canceled)

3. (original) The method of claim 1, wherein the iron carbohydrate complex has substantially no cross reactivity with anti-dextran antibodies.

4. (original) The method of claim 1, wherein the disease, disorder, or condition comprises anemia.

5. (original) The method of claim 4, wherein the anemia comprises iron deficiency anemia.

6. (original) The method of claim 4, wherein:

(i) the anemia comprises an iron deficiency anemia associated with chronic blood loss; acute blood loss; pregnancy; childbirth; childhood development; psychomotor and cognitive development in children; breath holding spells; heavy uterine bleeding; menstruation; chronic recurrent hemoptysis; idiopathic pulmonary siderosis; chronic internal bleeding; gastrointestinal bleeding; parasitic infections; chronic kidney disease; dialysis; surgery or acute trauma; and chronic ingestion of alcohol, chronic ingestion of salicylates, chronic ingestion of steroids; chronic ingestion of non-steroidal anti-inflammatory agents, or chronic ingestion of erythropoiesis stimulating agents;

(ii) the anemia is of a chronic disease selected from the group consisting of rheumatoid arthritis; cancer; Hodgkins leukemia; non-Hodgkins leukemia; cancer chemotherapy; inflammatory bowel disease; ulcerative colitis thyroiditis; hepatitis; systemic lupus erythematosus; polymyalgia rheumatica; scleroderma; mixed connective tissue disease; Sojgren's syndrome; congestive heart failure / cardiomyopathy; and idiopathic geriatric anemia;

(iii) the anemia is due to impaired iron absorption or poor nutrition;

(iv) the anemia is associated with Crohn's Disease; gastric surgery; ingestion of drug products that inhibit iron absorption; or chronic use of calcium.

7. (original) The method of claim 1 wherein the disease, disorder, or condition is selected from the group consisting of restless leg syndrome; blood donation; hair loss; and attention deficit disorder.

8. (original) The method of claim 1 wherein the single dosage unit of elemental iron is at least about 1.0 grams.

9. (original) The method of claim 1 wherein the single dosage unit of elemental iron is at least about 1.5 grams.

10. (original) The method of claim 1 wherein the single dosage unit of elemental iron is at least about 2.0 grams.

11. (canceled)

12. (original) The method of claim 1 wherein the single dosage unit of elemental iron is administered in about 5 minutes or less.

13. (original) The method of claim 1 wherein the iron carbohydrate complex is an iron carboxymaltose complex.

14. (original) The method of claim 13, wherein

(i) the iron carboxymaltose complex has a chemical formula of $[FeO_x(OH)_y(H_2O)_z]_n$ $[\{(C_6H_{10}O_5)_m(C_6H_{12}O_7)\}_l]_k$, where n is about 103, m is about 8, l is about 11, and k is about 4; contains about 28% elemental iron; and has a molecular weight of about 150,000 Da; or

(ii) the iron carboxymaltose complex is a polynuclear iron (III)-hydroxide 4(R)-(poly-(1→4)-*O*-α-glucopyranosyl)-oxy-2(R),3(S),5(R),6-tetrahydroxy-hexanoate.

15. (original) The method of claim 1, wherein the iron carbohydrate complex is an iron polyglucose sorbitol carboxymethyl ether complex.

16. (original) The method of claim 15, wherein the iron polyglucose sorbitol carboxymethyl ether complex is a polyglucose sorbitol carboxymethyl ether-coated non-stoichiometric magnetite complex.

17. (original) The method of claim 1, wherein

mean iron core size is at least about 1 nm but no greater than about 9 nm; or

mean size of a particle of the iron carbohydrate complex is no greater than about 35 nm.

18. (original) The method of claim 1, wherein the iron carbohydrate complex is administered parenterally.

19. (original) The method of claim 18, wherein

(i) parenteral administration comprises intravenous infusion and the single unit dose of iron carbohydrate complex is administered at a concentration of about 1000 mg elemental iron in about 200 ml to about 300 ml of diluent;

(ii) parenteral administration comprises bolus injection and the single unit dose of iron carbohydrate complex is administered at a concentration of about 1000 mg elemental iron in about 200 ml to about 300 ml of diluent; or

(iii) parenteral administration comprises intramuscular injection and the single unit dose of iron carbohydrate complex is administered at a concentration of about 500 mg elemental iron in less than about 10 ml diluent.

20. (original) The method of claim 1 further comprising a second administration of said iron carbohydrate complex upon recurrence of at least one symptom of the disease, disorder, or condition.

21. (new) The method of claim 1, wherein iron carbohydrate complex does not have an iron release rate of 115 µg/dl at a concentration of 2,000 µg/dl.

22. (new) The method of claim 1, wherein the iron carbohydrate complex is an iron polyisomaltose complex.

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