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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Indu J. ISAACS

Title: GLP-2 FORMULATIONS

Appl. No.: 09/750,022

Filing Date: December 29, 2000

Examiner: Chih Min Kam

Art Unit: 1653

AMENDMENT AND REPLY UNDER 37 CFR 1.111

Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

This communication is responsive to the Non-Final Office Action dated September 16, 2003, concerning the above-referenced patent application.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this document.

Remarks/Arguments begin on page 12 of this document.

Please amend the application as follows:

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Presently Amended) A glucagon-like peptide 2 (GLP-2) formulation comprising:

(a) a medically useful amount of a naturally occurring ~~glucagon-like peptide-2 (~~GLP-2~~)~~ or an analog thereof;

(b) a phosphate buffer in an amount sufficient to adjust the pH of the formulation to a physiologically tolerable level;

(c) L-histidine; and

(d) a bulking agent selected from the group consisting of mannitol and sucrose.

2. (Original) The GLP-2 formulation of claim 1, wherein the pH of the formulation is greater than about 6.0.

3. (Original) The GLP-2 formulation according to claim 2, wherein the pH of the formulation is from about 6.9 to about 7.9.

4. (Original) The GLP-2 formulation of claim 3, wherein the pH of the formulation is from about 7.3 to about 7.4.

5. (Original) The GLP-2 formulation of claim 1, wherein the GLP-2 peptide or analog thereof is present at a concentration of about 0.1 to about 50 mg/ml.

6. (Original) The GLP-2 formulation of claim 5, wherein the GLP-2 peptide or analog thereof is present at a concentration of about 5 to about 40 mg/ml.

7. (Original) The GLP-2 formulation of claim 6, wherein the GLP-2 peptide or analog thereof is present at a concentration of about 7 to about 30 mg/ml.

8. (Original) The GLP-2 formulation of claim 7, wherein the GLP-2 peptide or analog thereof is present at a concentration of about 10 to about 20 mg/ml.

9. (Original) The GLP-2 formulation of claim 8, wherein the L-histidine is present in an amount of about 0.5 to about 1%.

10. (Original) The GLP-2 formulation of claim 9, wherein the bulking agent is mannitol.

11. (Original) The GLP-2 formulation of claim 10, wherein the mannitol is present at a concentration of about 2 to about 5%.

12. (Original) The GLP-2 formulation of claim 11, wherein the mannitol is present at a concentration of about 2.5 to about 3.5%.

13. (Original) The GLP-2 formulation of claim 1, wherein the GLP-2 peptide is selected from the group consisting of a mammalian GLP-2 peptide, a vertebrate GLP-2 peptide, and a human GLP-2 peptide.

14. (Previously Presented) The GLP-2 formulation of claim 13, wherein the GLP-2 peptide has the sequence of a GLP-2 species from an animal selected from the group consisting of a primate, rat, mouse, porcine species, oxine species, bovine species, degu, hamster, guinea pig, fish, chicken, and human.

15. (Previously presented) The GLP-2 formulation of claim 14, wherein the GLP-2 peptide is h(Gly2)GLP-2.

16. (Original) The GLP-2 formulation of claim 1, wherein the GLP-2 analog is identified by a process comprising:

(a) screening peptides against cells genetically engineered to produce the GLP-2 receptor, and

(b) identifying peptides which bind to the GLP-2 receptor, wherein such peptides are identified as GLP-2 peptides useful in the formulation of claim 1.

17. (Original) The GLP-2 formulation of claim 1, wherein the GLP-2 peptide is an analog of natural GLP-2, the analog having:

(a) one or more amino acid substitutions, additions, deletions, or modifications; and

(b) biological activity.

18. (Original) The GLP-2 formulation of claim 1, wherein the GLP-2 peptide is an analog which has been altered to confer resistance to endogenous enzymes.

19. (Original) The GLP-2 formulation of claim 18, wherein the alteration comprises substitution of the alanine residue at position 2 of GLP-2 with another suitable amino acid.

20. (Original) The GLP-2 formulation of claim 19, wherein the alanine residue at position 2 is substituted with glycine or serine.

21. (Original) The GLP-2 formulation of claim 1, wherein the GLP-2 analog is a GLP-2 receptor antagonist.

22. (Original) The GLP-2 formulation of claim 1 in lyophilized form.

23. (Original) The lyophilized formulations of claim 22, comprising less than about 5% water by weight.

24. (Original) The lyophilized formulations of claim 23, comprising 2% or less water by weight.

25. (Presently Amended) The GLP-2 formulation of claim ~~1~~15, which is stable at ambient temperature for up to at least 6 months, as evidenced by GLP-2 peptide degradation of less than about 5% during this time period.

26. (Original) The GLP-2 formulation of claim 25, wherein less than about 3 to about 4% peptide degradation is observed after storage of the GLP-2 formulation during the time period.

27. (Original) The GLP-2 formulation of claim 26, wherein less than about 1 to about 2% peptide degradation is observed after storage of the GLP-2 formulation during the time period.

28. (Original) The GLP-2 formulation of claim 1, which is stable at a temperature of about 4°C for up to at least 18 months, as evidenced by GLP-2 peptide degradation of less than about 5% during this time period.

29. (Original) The GLP-2 formulation of claim 28, wherein less than about 3 to about 4% peptide degradation is observed after storage of the GLP-2 during the time period.

30. (Original) The GLP-2 formulation of claim 29, wherein less than about 2% peptide degradation is observed after storage of the GLP-2 formulation during the time period.

31. (Original) A GLP-2 formulation comprising:

(a) about 0.1 to about 50 mg/ml of a GLP-2 peptide or an analog thereof;

(b) a phosphate buffer in an amount sufficient to adjust the pH of the formulation to a pharmaceutically tolerable level;

(c) about 0.5 to about 1% L-histidine; and

(d) about 2 to about 5% mannitol.

32. (Previously Presented) The GLP-2 formulation of claim 31, wherein the GLP-2 is h(Gly2)GLP-2.

33. (Original) The GLP-2 formulation of claim 32, wherein the formulation is lyophilized.

34. (Original) The GLP-2 formulation of claim 32, wherein the pH of the formulation is selected from the group consisting of greater than about 6.0, and from about 6.9 to about 7.9.

35. (Original) The GLP-2 formulation of claim 34, wherein the pH of the formulation is from about 7.3 to about 7.4.

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