IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Amir Shojaei

Application No.: 11/383,066 — Confirmation No.:

Filed: May 12, 2006 — Art Unit: N/A

For: CONTROLLED DOSE DRUG DELIVERY SYSTEM — Examiner: Not Yet Assigned

FIRST PRELIMINARY AMENDMENT

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

Dear Sir:

INTRODUCTORY COMMENTS

Prior to examination on the merits, please amend the above-identified U.S. patent application as follows:

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

Remarks begin on page 6 of this paper.

LISTING OF CLAIMS

1. (Original) A pharmaceutical composition comprising:

(a) an immediate release bead comprising at least one amphetamine salt;

(b) a first delayed release bead comprising at least one amphetamine salt; and

(c) a second delayed release bead comprising at least one amphetamine salt;

wherein the first delayed release bead provides pulsed release of the at least one amphetamine salt and the second delayed release bead provides sustained release of the at least one amphetamine salt.

2. (Original) The pharmaceutical composition of claim 1, wherein the first delayed release bead and the second delayed release bead comprise an enteric coating.

3. (Original) The pharmaceutical composition of claim 2, wherein the enteric coating is pH dependent.

4. (Original) The pharmaceutical composition of claim 2, wherein the first delayed release bead and the second delayed release bead comprise different enteric coatings.

5. (Original) The pharmaceutical composition of claim 2, wherein the first delayed release bead and the second delayed release bead comprise the same enteric coating.

6. (Original) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition is bioequivalent to ADDERALL® XR followed by an immediate release amphetamine formulation administered 8 hours after the ADDERALL® XR;

wherein the combined dosage of the ADDERALL® XR and the immediate release formulation is equal to the dosage of the pharmaceutical composition.

7. (Original) The pharmaceutical composition of claim 1, wherein administration of a 37.5 mg dose of the pharmaceutical composition to a human patient results in a *d*-amphetamine C_{max} of about 50 ng/ml.

8. (Original) The pharmaceutical composition of claim 1, wherein the *d*-amphetamine area under the curve from time 0 to the last measured time ($AUC_{0\text{-last}}$) after administration of a 37.5 mg dose of the pharmaceutical composition to a human patient is about 1058 ng·hr/ml.

9. (Original) The pharmaceutical composition of claim 1, wherein the *d*-amphetamine area under the curve from time 0 to time infinity ($AUC_{0\text{-inf}}$) after administration of a 37.5 mg dose of the pharmaceutical composition to a human patient is about 1085 ng·hr/ml.

10. (Original) The pharmaceutical composition of claim 1, wherein the *d*-amphetamine T_{max} is about 8.2 hours after administration of a 37.5 mg dose of the pharmaceutical composition to a human patient.

11. (Original) The pharmaceutical composition of claim 1, wherein the *l*-amphetamine C_{max} after administration of a 37.5 mg dose of the pharmaceutical composition to a human patient is about 15 ng/ml.

12. (Original) The pharmaceutical composition of claim 1, wherein the *l*-amphetamine area under the curve from time 0 to the last measured time ($AUC_{0\text{-last}}$) after administration of a 37.5 mg dose of the pharmaceutical composition to a human patient is about 354 ng·hr/ml.

13. (Original) The pharmaceutical composition of claim 1, wherein the *l*-amphetamine area under the curve from time 0 to time infinity ($AUC_{0\text{-inf}}$) after administration of a 37.5 mg dose of the pharmaceutical composition to a human patient is about 373 ng·hr/ml.

14. (Original) The pharmaceutical composition of claim 1, wherein the *l*-amphetamine T_{max} is about 8.4 hours after administration of a 37.5 mg dose of the pharmaceutical composition to a human patient.

15. (Original) The pharmaceutical composition of claim 1, wherein the immediate release bead and at least one delayed release bead are present on a single core.

16. (Original) The pharmaceutical composition of claim 1, wherein the immediate release bead and at least one delayed release bead are present on different cores.

17. (Original) The pharmaceutical composition of claim 1, wherein the at least one amphetamine salt is coated onto a core.

18. (Original) The pharmaceutical composition of claim 1, wherein the at least one amphetamine salt is incorporated into a core.

19. (Original) The pharmaceutical composition of claim 2, which further comprises a protective layer over at least one enteric coating.

20. (Original) The pharmaceutical composition of claim 2, which further comprises a protective layer between the amphetamine salt and at least one enteric coating.

21. (Original) The pharmaceutical composition of claim 1, wherein the at least one amphetamine salt is selected from the group consisting of dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate monohydrate, amphetamine sulfate, and mixtures thereof.

22. (Original) The pharmaceutical composition of claim 21, wherein the at least one amphetamine salt is a mixture of dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate monohydrate, and amphetamine sulfate.

23. (Original) The pharmaceutical composition of claim 1, wherein the composition does not exhibit a food effect.

24. (Original) The composition of claim 6, wherein the amount of at least one amphetamine salt is about 12.5 mg.

25. (Original) The composition of claim 6, wherein the amount of at least one amphetamine salt is about 18.75 mg.

26. (Original) The composition of claim 6, wherein the amount of at least one amphetamine salt is about 25 mg.

27. (Original) The composition of claim 6, wherein the amount of at least one amphetamine salt is about 31.25 mg.

28. (Original) The composition of claim 6, wherein the amount of at least one amphetamine salt is about 37.5 mg.

29. (Original) The composition of claim 6, wherein the amount of at least one amphetamine salt is about 43.75 mg.

30. (Original) The composition of claim 6, wherein the amount of at least one amphetamine salt is about 50 mg.

31. (Original) The composition of claim 6, wherein the amount of at least one amphetamine salt is about 62.5 mg.

32. (Original) The composition of claim 6, wherein the amount of at least one amphetamine salt is about 75 mg.

33-58. (Canceled)

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