Docket No.: 085199-0034
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	:	Customer Number: 20277
Amir SHOJAEI	:	Confirmation Number: 7083
Application No.: 11/383,066	:	Group Art Unit: 1618
Filed: May 12, 2006	:	Examiner: Micah Paul YOUNG

For: CONTROLLED DOSE DRUG DELIVERY SYSTEM

AMENDMENT

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

Sir:

INTRODUCTION

This is in response to the non-final Office Action mailed October 2, 2009.

A petition for a One-Month Extension of Time accompanies this response.

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of the claims beginning on page 3 of this paper.

Remarks/Arguments begin on page 7 of this paper.

Amendments to the Specification

Please replace the paragraph beginning at page 16, line 7 with the following paragraph:

"Immediate" and "delayed" release refer to the onset of release in relationship to administration of the drug. "Immediate" means that the release of drug begins very soon, within a relatively short time after administration, e.g. a few minutes or less. "Delayed" means that the release of drug is postponed, and begins or is triggered some period of time after administration (e.g., the lag time), typically a relatively long period of time, e.g. more than one hour.

Amendments to the 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. (Canceled)

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 nghr/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 nghr/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 nghr/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 nghr/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. (Currently amended) The composition of claim [6] 1, wherein the amount of at least one amphetamine salt is about 12.5 mg.

25. (Currently amended) The composition of claim [6] 1, wherein the amount of at least one amphetamine salt is about 18.75 mg.

26. (Currently amended) The composition of claim [6] 1, wherein the amount of at least one amphetamine salt is about 25 mg.

27. (Currently amended) The composition of claim [6] 1, wherein the amount of at least one amphetamine salt is about 31.25 mg.

28. (Currently amended) The composition of claim [6] 1, wherein the amount of at least one amphetamine salt is about 37.5 mg.

29. (Currently amended) The composition of claim [6] 1, wherein the amount of at least one amphetamine salt is about 43.75 mg.

30. (Currently amended) The composition of claim [6] 1, wherein the amount of at least one amphetamine salt is about 50 mg.

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