IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Mark Eller	Confirmation No.:	2127
Application No.:	13/872,997	Art Unit:	1629
Filed:	April 29, 2013	Examiner:	Gembeh, Shirley
For:	METHOD OF ADMINISTRATION OF GAMMA HYDROXYBUTYRATE WITH MONOCARBOXYLATE TRANSPORTERS	Atty. Docket No.:	13314-004-999

RESPONSE TO NOTICE OF NON-COMPLIANT AMENDMENT (37 CFR 1.121) AND SUPPLEMENTAL AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.111

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

Sir:

In response to the Notice of Non-Compliant Amendment (37 CFR 1.121) mailed November 5, 2013, and the non-final Office Action mailed September 13, 2013, and in accordance with the Rules of Practice, Applicant herein encloses a Supplemental Amendment and Response.

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

Remarks begin on page 8 of this paper.

Ranbaxy Ex. 1027
IPR Petition - USP 8,772,306

AMENDMENTS TO THE CLAIMS

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

Listing of claims:

1. (Currently Amended) A method for treating a patient who is suffering from excessive daytime sleepiness, cataplexy, sleep paralysis, apnea, narcolepsy, sleep time disturbances, hypnagogic hallucinations, sleep arousal, insomnia, or nocturnal myoclonus with gamma-hydroxybutyrate (GHB) or a salt thereof, said method comprising:

orally administering to the patient in need of treatment an [[adjusted]] effective dosage amount of the GHB or salt thereof when the patient is receiving a concomitant administration of valproate.

2. (Currently Amended) The method in accordance with claim 1, wherein the [[adjusted]] effective dosage amount is ~~reduced by~~ at least about a 15% reduction of the dose of the GHB or salt thereof normally given to the patient.

3. (Currently Amended) The method in accordance with claim 1, wherein the [[adjusted]] effective dosage amount is ~~reduced between the range~~ a reduction of about 1% to 5%, about 5% to 10%, about 10% to 15%, about 15% to 20%, about 20% to 25%, about 25% to 30%, about 30% to 35%, about 35% to 40%, about 40% to 45%, or about 45% to 50%, relative to the dose of the GHB or salt thereof normally given to the patient.

4. (Currently Amended) The method in accordance with claim 1, wherein the GHB salt is administered at a normal dose of between 1 gram and 10 grams per day.

5. (Original) The method in accordance with claim 1, wherein the patient is suffering from narcolepsy.

6. (Original) The method in accordance with claim 1, further comprising administering aspirin to the patient.

7. (Currently Amended) A method of safely administering GHB or a salt thereof for excessive daytime sleepiness, cataplexy, sleep paralysis, apnea, narcolepsy, sleep time disturbances, hypnagogic hallucinations, sleep arousal, insomnia, or nocturnal myoclonus in a human patient, said method comprising:

determining if the patient has taken, or will take, a concomitant dose of valproate; and

orally administering a reduced amount of the GHB or salt thereof to the patient compared to a normal dose of between 1 and 10 grams per day ~~so as to diminish the additive effects of the GHB or salt thereof when administered with valproate~~.

8. (Original) The method in accordance with claim 7, wherein the amount of GHB or salt thereof is reduced at least 10% to 30% of the normal dose for the patient.

9. (Original) The method in accordance with claim 7, wherein the amount of GHB or salt thereof is reduced at least 15% of the normal dose for the patient.

10. (Cancelled).

11. (Original) The method in accordance with claim 7, herein the valproate is administered within two weeks of administration of the GHB or salt thereof.

12. (Original) The method in accordance with claim 7, wherein the valproate is administered within three days of administration of the GHB or salt thereof.

13. (Original) The method in accordance with claim 7, wherein the patient is suffering from narcolepsy.

14. (Original) The method in accordance with claim 7, further comprising administering aspirin to the patient.

15. (Currently Amended) A method for treating a patient who is suffering from narcolepsy, said method comprising:

administering a therapeutically effective amount of a formulation containing a GHB salt to a patient starting at a concentration of between 350 and 750 mg/ml [[and]] with a pH of between 6 and 10, said formulation being administered in two doses ~~before bed and 1 to 2 hours thereafter~~;

determining if the patient is also being administered valproate;

warning of a potential drug/drug interaction due to the combination of valproate and the GHB salt; and

recommending reducing the dose of the GHB salt at least 15% ~~to compensate for the effect caused by valproate~~.

16. (Original) The method in accordance with claim 15, wherein the valproate is administered within two weeks of administration of the GHB salt.

17. (Original) The method in accordance with claim 15, wherein the valproate is administered within three days of administration of the GHB salt.

18. (Original) The method in accordance with claim 15, wherein the GHB salt is administered starting at a concentration of between 450 to 550 mg/ml.

19. (Original) The method in accordance with claim 15, wherein the GHB formulation has a pH between 6.5 and 8.

20. (Original) The method in accordance with claim 15, further comprising administering the reduced dose of the GHB salt to the patient.

21. (Original) The method in accordance with claim 15, wherein the GHB salt comprises a single or a mixture of salts of GHB selected from the group consisting of a sodium salt of hydroxybutyrate (Na•GHB), a potassium salt of gamma-hydroxybutyrate (K•GHB), a magnesium salt of gamma-hydroxybutyrate (Mg•$(GHB)_2$), and a calcium salt of gamma-hydroxybutyrate (Ca•$(GHB)_2$).

22. (Original) The method in accordance with claim 15, further comprising administering aspirin to the patient.

23. (Currently Amended) The method in accordance with claim 1, wherein the [[adjusted]] effective dosage amount is reduced from 4.5 to 9 grams per day ~~relative to the dosage approved by the FDA for treatment~~.

24. (Currently Amended) The method in accordance with claim 2, wherein the dose normally given to the patient is from 4.5 to 9 grams per day ~~the dosage approved by the FDA for treatment~~.

25. (Currently Amended) The method in accordance with claim 4, wherein the normal dose is from 4.5 to 9 grams per day ~~the dosage approved by the FDA for treatment~~.

26. (Currently Amended) The method in accordance with claim 1, wherein the [[adjusted]] effective dosage amount is between 3 grams and 7 grams per day.

27. (Currently Amended) The method in accordance with claim 1, wherein the [[adjusted]] effective dosage amount is between 3.5 grams and 4 grams per day.

28. (New) A method for treating a patient who is suffering from narcolepsy, said method comprising:

administering a therapeutically effective amount of a formulation containing a GHB salt to a patient;

determining if the patient is also being administered valproate;

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