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(72) Inventor; and

(71) Applicant : ROYSTER, JR., George, E. [US/US]; 300 Treybrooke Circle, Apt. 31, Greenville, NC 27834 (US).

(74) Agent: CORTINA, Jose, A.; Ward and Smith, P.A., P.O. Box 867, 1001 College Court, New Bern, NC 28563-0867 (US).

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(54) Title: METHODS AND COMPOSITIONS FOR TREATING OR PREVENTING SYMPTOMS OF HORMONAL VARIATIONS

(57) Abstract: The present invention relates to methods, compositions, and kits for treating or preventing symptoms of hormonal variation. The method comprises the steps of administering an effective amount of a receptor antagonist to a subject having one or more symptoms of hormonal variations. The receptor antagonist binds to at least one receptor selected from a serotonin type 2A (5-HT.sub.2A) and/or a dopamine type 2 (D.sub.2) receptors.



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AMENDED CLAIMS

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1. A method for treatment or prevention of symptoms of hormonal variation, comprising:

identifying a subject having one or more symptoms of hormonal variations; and
administering an effective amount of at least one of Dextromethorphan and Dextrophan to the subject.

2. (Cancelled)

3. The method of claim 1 wherein said Dextromethorphan is DextromethorphanHBr.

4. (Cancelled)

5. (Cancelled)

6. (Cancelled)

7. The method of claim 1 wherein said symptoms of hormonal variation comprise hot flashes and night sweats.

8. The method of claim 1 wherein the effective amount of the at least one of Dextromethorphan and Dextrophan is from 0.1 to 100 mg per day.

9. The method of claim 1 wherein the subject is a female.

10. The method of claim 1 wherein the subject is a male.

11. A method for treatment or prevention of symptoms of hormonal variation, comprising: identifying a subject having one or more symptoms of hormonal variations; and

administering an effective amount of at least one of Dextromethorphan and Dextrophan-and another compound known to reduce or prevent the symptoms of hormonal variation to the subject.

12. (Cancelled)

13. The method of claim 11 wherein said another compound is Gabapentin.

14. The method of claim 13 wherein the amount of at least one of Dextromethorphan and Dextrophan administered is from 0.1 to 100 mg per day and the amount of Gabapentin administered is from 1 mg to 900 mg per day.

15. A pharmaceutical composition for treatment or prevention of symptoms of hormonal variation, comprising:

an effective amount of a at least one of Dextromethorphan and Dextrophan; and

wherein the at least one of Dextromethorphan and Dextrophan is used to treat or prevent symptoms of hormonal variation.

16. A kit for treatment or prevention of symptoms of hormonal variation, comprising:

an effective amount of at least one of Dextromethorphan and Dextrophan; and

instructions for performing at least one method of the invention.

17. (Cancelled)

18. The kit of claim 16, wherein said Dextromethorphan is DextromethorphanHBr.

19. The kit of claim 16, further comprising a pharmaceutically acceptable form of at least one of Dextromethorphan and Dextrophan in at least one of oral dosage form, injection, inhalation, and transdermal patch.

20. The kit of claim 18, wherein said oral dosage form comprises a solution, gel, tablet, capsule, or powder.

21. The kit of claim 18, wherein said oral dosage form comprises a controlled-release dosage form, a rapidly dispersed dosage form with a porous network of a matrix composition, or a solid rapidly disintegrating dosage form.

22. The kit of claim 16, wherein the oral dosage form comprises at least a microparticle composition and a biodegradable and biocompatibly acceptable microparticle polymer carrier.

23. The kit of claim 16, wherein the oral dosage form comprises at least a sustained-release microparticle produced by dissolving at least one of Dextromethorphan and Dextrophan in a solvent with a biodegradable and biocompatible polymer to form an organic phase, and extracting the solvent to form microparticles.

24. The kit of claim 16, wherein the oral dosage form comprises a microencapsulated pharmaceutical composition having a selected release profile prepared by a method for preparing microparticles, comprising:

(a) preparing an emulsion that comprises a first phase and a second phase, wherein the first phase comprises at least one of Dextromethorphan and Dextrophan, a polymer, and a solvent for the polymer;

(b) quenching the emulsion in a quench liquid to form microparticles containing at least one of Dextromethorphan and Dextrophan;

(c) selecting a degree of intermediate drying of the microparticles to be performed so that the selected release profile is achieved;

(d) washing the microparticles; and

(e) final drying the microparticles.

25. The kit of claim 16, wherein the oral dosage form is a multi-phasic sustained-release microparticle composition, prepared by a process comprising: dissolving in a solvent at least one of Dextromethorphan and Dextrorphan and a biodegradable and biocompatible polymer to form an organic phase; extracting the solvent to form microparticles; and combining microparticles having a plurality of sizes to thereby form a composition that delivers at least one of Dextromethorphan and Dextrorphan in a multi-phasic manner.

26. The kit of claim 16, comprising at least one of Dextromethorphan and Dextrorphan and at least one substance selected from the group consisting of nutrients, vitamins, other active ingredients, sweeteners, flavouring agents, colouring agents, surfactants, preservatives, antioxidants, viscosity enhancers, and minerals.

27. The kit of claim 16, comprising multiple containers containing at least one of Dextromethorphan and Dextrorphan.

28. The kit of claim 16, wherein the effective amount of at least one of Dextromethorphan and Dextrorphan is given to a female.

29. The kit of claim 16, wherein the effective amount of at least one of Dextromethorphan and Dextrorphan is given to a male.

STATEMENT UNDER ARTICLE 19(1)

Claims 3 and 18 have been amended to reflect a change in dependency since they originally depended from claims cancelled by the present Amendment. Claims 2, 4-6, 12, and 17 have been cancelled by the present Amendment. Claims 1, 8, 11, 14,-16, 19 and 23-29 have been amended by deleting reference to the term "receptor antagonist" and related language and inserting reference to the phrase "at least one of Dextromethorphan and Dextrorphan." Accordingly, the claims as presently amended are not limited to a particular mechanism of action. Support for these amendments can be found in claims 2, 12, and 17 as originally filed and generally throughout the specification as originally filed, for example, at paragraphs [0049-0064] of the original application. No new matter has been added.