PATENT

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Applicants:	Myers et al.	Examiner:	Janet L. Epps-Smith
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For:	SUBLINGUAL AND BUCCAL FILM COMPOSITIONS		

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Dated: January 2, 2014

Signature: /Stephen J. Brown/ Stephen Brown

AMENDMENT AND RESPONSE TO OFFICE ACTION

Madam:

In response to the Office Action dated November 7, 2013, a response to which is due by February 7, 2014, the Applicants offer the following amendments and remarks.

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

Remarks/Arguments begin on page 9 of this submission.

Amendments to the Claims:

This listing of claims shall replace all previous listings of claims:

1. (Currently Amended) An orally dissolving film formulation comprising from about 2 to about 16 mg of buprenorphine and from about 0.5 to about 4 mg of naloxone, wherein said formulation provides an in vivo plasma profile having a mean C_{max} of between about 0.6 ng/ml and about 5.7 ng/ml for buprenorphine and an in vivo plasma profile having a mean C_{max} of between about 41 pg/ml to about 324 pg/ml for naloxone; wherein said film formulation further comprises one or more polymers and the ratio of a free base equivalent amount of said buprenorphine to the total amount of said one or more polymers is from about 1:0.6 to about 1:25 by weight.

2. (Original) The film formulation of claim 1, comprising about 2 mg of buprenorphine and about 0.5 mg of naloxone, wherein said formulation provides an in vivo plasma profile having a mean C_{max} of between about 0.6 ng/ml and about 1.0 ng/ml for buprenorphine and an in vivo plasma profile having a mean C_{max} of between about 41 pg/ml to about 65 pg/ml for naloxone.

3. (Original) The film formulation of claim 1, comprising about 4 mg of buprenorphine and about 1 mg of naloxone, wherein said formulation provides an in vivo plasma profile having a mean C_{max} of between about 1.0 ng/ml and about 1.7 ng/ml for buprenorphine and an in vivo plasma profile having a mean C_{max} of between about 64 pg/ml to about 102 pg/ml for naloxone.

4. (Original) The film formulation of claim 1, comprising about 8 mg of buprenorphine and about 2 mg of naloxone, wherein said formulation provides an in vivo plasma profile having a mean C_{max} of between about 1.8 ng/ml and about 2.9 ng/ml for buprenorphine and an in vivo plasma profile having a mean C_{max} of between about 75 pg/ml to about 119 pg/ml for naloxone.

5. (Original) The film formulation of claim 1, comprising about 12 mg of buprenorphine and about 3 mg of naloxone, wherein said formulation provides an in vivo plasma profile having a mean C_{max} of between about 2.5 ng/ml and about 4.1 ng/ml for buprenorphine and an in vivo plasma profile having a mean C_{max} of between about 159 pg/ml to about 250 pg/ml for naloxone.

6. (Original) The film formulation of claim 1, comprising about 16 mg of buprenorphine and about 4 mg of naloxone, wherein said formulation provides an in vivo plasma profile having a mean C_{max} of between about 3.6 ng/ml and about 5.7 ng/ml for buprenorphine and an in vivo plasma profile having a mean C_{max} of between about 207 pg/ml to about 324 pg/ml for naloxone.

7. (Currently Amended) An orally dissolving film formulation comprising from about 2 to about 16 mg of buprenorphine and from about 0.5 to about 4 mg of naloxone, wherein said formulation provides an in vivo plasma profile having a mean C_{max} of between about 0.7 ng/ml and about 6.9 ng/ml for buprenorphine and an in vivo plasma profile having a mean C_{max} of between about 40 pg/ml to about 405 pg/ml for naloxone; wherein said film formulation further comprises one or more polymers and the ratio of a free base equivalent amount of said buprenorphine to the total amount of said one or more polymers is from about 1:0.6 to about 1:25 by weight.

8. (Original) The film formulation of claim 7, comprising about 2 mg of buprenorphine and about 0.5 mg of naloxone, wherein said formulation provides an in vivo plasma profile having a mean C_{max} of between about 0.7 ng/ml and about 1.2 ng/ml for buprenorphine and an in vivo plasma profile having a mean C_{max} of between about 40 pg/ml to about 64 pg/ml for naloxone.

9. (Original) The film formulation of claim 7, comprising about 4 mg of buprenorphine and about 1 mg of naloxone, wherein said formulation provides an in vivo plasma profile having a mean C_{max} of between about 1.2 ng/ml and about 2.0 ng/ml for buprenorphine and an in

vivo plasma profile having a mean C_{max} of between about 72 pg/ml to about 113 pg/ml for naloxone.

10. (Original) The film formulation of claim 7, comprising about 8 mg of buprenorphine and about 2 mg of naloxone, wherein said formulation provides an in vivo plasma profile having a mean C_{max} of between about 2.1 ng/ml and about 3.4 ng/ml for buprenorphine and an in vivo plasma profile having a mean C_{max} of between about 104 pg/ml to about 163 pg/ml for naloxone.

11. (Original) The film formulation of claim 7, comprising about 12 mg of buprenorphine and about 3 mg of naloxone, wherein said formulation provides an in vivo plasma profile having a mean C_{max} of between about 3.3 ng/ml and about 5.3 ng/ml for buprenorphine and an in vivo plasma profile having a mean C_{max} of between about 196 pg/ml to about 308 pg/ml for naloxone.

12. (Original) The film formulation of claim 7, comprising about 16 mg of buprenorphine and about 4 mg of naloxone, wherein said formulation provides an in vivo plasma profile having a mean C_{max} of between about 4.3 ng/ml and about 6.9 ng/ml for buprenorphine and an in vivo plasma profile having a mean C_{max} of between about 259 pg/ml to about 405 pg/ml for naloxone.

13. (Currently Amended) An orally dissolving film formulation comprising buprenorphine and naloxone that is bioequivalent to a SUBOXONE® tablet containing from about 2 to about 16 mg of buprenorphine and from about 0.5 to about 4 mg of naloxone such that said formulation provides an in vivo plasma profile having a mean C_{max} of between about 0.6 ng/ml and about 5.7 ng/ml for buprenorphine and an in vivo plasma profile having a mean C_{max} of between about 41 pg/ml to about 324 pg/ml for naloxone; wherein said film formulation further comprises one or more polymers and the ratio of a free base equivalent amount of said buprenorphine to the total amount of said one or more polymers is from about 1:0.6 to about 1:25 by weight.

14. (Original) The film formulation of claim 13 wherein said film formulation comprising buprenorphine and naloxone is bioequivalent to a SUBOXONE® tablet containing about 2 mg of buprenorhphine and about 0.5 mg of naloxone such that said formulation provides an in vivo plasma profile having a mean C_{max} of between about 0.6 ng/ml and about 1.0 ng/ml for buprenorphine and an in vivo plasma profile having a mean C_{max} of between about 41 pg/ml to about 65 pg/ml for naloxone.

15. (Original) The film formulation of claim 13 wherein said film formulation comprising buprenorphine and naloxone is bioequivalent to a SUBOXONE® tablet containing about 4 mg of buprenorhphine and about 1 mg of naloxone such that said formulation provides an in vivo plasma profile having a mean C_{max} of between about 1.0 ng/ml and about 1.7 ng/ml for buprenorphine and an in vivo plasma profile having a mean C_{max} of between about 64 pg/ml to about 102 pg/ml for naloxone.

16. (Original) The film formulation of claim 13 wherein said film formulation comprising buprenorphine and naloxone is bioequivalent to a SUBOXONE® tablet containing about 8 mg of buprenorhphine and about 2 mg of naloxone such that said formulation provides an in vivo plasma profile having a mean C_{max} of between about 1.8 ng/ml and about 2.9 ng/ml for buprenorphine and an in vivo plasma profile having a mean C_{max} of between about 75 pg/ml to about 119 pg/ml for naloxone.

17. (Original) The film formulation of claim 13 wherein said film formulation comprising buprenorphine and naloxone is bioequivalent to a SUBOXONE® tablet containing about 12 mg of buprenorhphine and about 3 mg of naloxone such that said formulation provides an in vivo plasma profile having a mean C_{max} of between about 2.5 ng/ml and about 4.1 ng/ml for buprenorphine and an in vivo plasma profile having a mean C_{max} of between about 159 pg/ml to about 250 pg/ml for naloxone.

18. (Original) The film formulation of claim 13 wherein said film formulation comprising buprenorphine and naloxone is bioequivalent to a SUBOXONE® tablet containing about 16 mg of buprenorhphine and about 4 mg of naloxone such that said formulation provides an in

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