PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	Myers et al.	Examiner:	Janet L. Epps-Smith
Serial No.:	12/537,571	Group Art Unit:	1633
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Filed:	August 7, 2009	Dated:	February 29, 2012
For:	Sublingual and Buccal Film Compositions		

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Dated: February 29, 2012

Signature: Christine Briscoe/cbriscoe/

AMENDMENT AND RESPONSE

Sir:

In response to the office action dated August 31, 2011, a response to which is due by February 29, 2012 in view of the concurrently filed petition for three month extension of time, please amend the application as follows:

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

Remarks begin on page 7 of this paper.

Amendments to the Claims:

This listing of claims shall replace all previous listings in this application:

1. (Currently Amended) A film dosage composition comprising:
    a. A polymeric carrier matrix;
    b. A therapeutically effective amount of buprenorphine or a pharmaceutically acceptable salt thereof;
    c. A therapeutically effective amount of naloxone or a pharmaceutically acceptable salt thereof; and
    d. A buffer in an amount to provide a local pH ~~of~~ for said composition of a value sufficient to optimize absorption of said buprenorphine, wherein said local pH is from about 2 to about 3.5 in the presence of saliva.
2. (Canceled).
3. (Currently Amended) The composition of claim 1 ~~2~~, wherein the local pH of said composition is from about 3 to about 3.5 [[4]].
4. (Original) The composition of claim 1, wherein said film dosage composition provides a bioequivalent absorption of buprenorphine to that of a tablet having an equivalent amount of buprenorphine or a pharmaceutically acceptable salt thereof.
5. (Original) The composition of claim 1, wherein said polymeric carrier matrix comprises at least one polymer in an amount of at least 25% by weight of said composition.
6. (Original) The composition of claim 1, wherein said buffer is present in an amount of from about 2:1 to about 1:5 by weight of buffer to buprenorphine.
7. (Original) The composition of claim 1, wherein said polymeric carrier matrix comprises at least one self-supporting film forming polymer.
8. (Original) The film dosage composition of claim 1, wherein said buprenorphine is present in an amount of from about 2 mg to about 16 mg per dosage.
9. (Original) The film dosage composition of claim 1, wherein said buffer comprises sodium citrate, citric acid, and combinations thereof.

10. (Original) The film dosage composition of claim 1, wherein said buffer comprises acetic acid, sodium acetate, and combinations thereof.
11. (Currently Amended) A film dosage composition comprising:
    a. A polymeric carrier matrix;
    b. A therapeutically effective amount of buprenorphine or a pharmaceutically acceptable salt thereof;
    c. A therapeutically effective amount of naloxone or a pharmaceutically acceptable salt thereof; and
    d. A buffer in an amount sufficient to inhibit the absorption of said naloxone, while also optimizing absorption of said buprenorphine when administered orally.
12. (Currently Amended) The composition of claim 11, wherein said composition has a local pH of about 2 to about 3.5 [[4]].
13. (Currently Amended) The composition of claim 11, wherein said composition has a local pH of about 3 to about 3.5 ~~said buffer is present in an amount sufficient to provide a therapeutically adequate absorption of buprenorphine~~.
14. (Currently Amended) The composition of claim 13, wherein ~~a therapeutically adequate absorption of buprenorphine comprises~~ said buffer is present in an amount sufficient to provide a bioequivalent level of absorption of buprenorphine as a tablet having an equivalent amount of buprenorphine or a pharmaceutically acceptable salt thereof.
15. (Currently Amended) A film dosage composition comprising:
    a. A polymeric carrier matrix;
    b. A therapeutically effective amount of buprenorphine or a pharmaceutically acceptable salt thereof;
    c. A therapeutically effective amount of naloxone or a pharmaceutically acceptable salt thereof; and
    d. A buffering system;

    wherein said buffering system comprises a buffer capacity sufficient to maintain the ionization of naloxone during the time which said composition is in the oral

cavity of a user, and also sufficient to optimize the absorption of said buprenorphine.

16. (Currently Amended) The composition of claim 15, wherein said composition has a local pH of about 2 to about 3.5 [[4]].
17. (Currently Amended) A method of treating narcotic dependence of a user, comprising the steps of:
    a. providing a composition comprising:
        i. A polymeric carrier matrix;
        ii. A therapeutically effective amount of buprenorphine or a pharmaceutically acceptable salt thereof;
        iii. A therapeutically effective amount of naloxone or a pharmaceutically acceptable salt thereof; and
        iv. A buffer in an amount to provide a local pH of about 2 to about 3.5 for said composition of a value sufficient to optimize absorption of said buprenorphine and also sufficient to inhibit absorption of said naloxone; and
    b. administering said composition to the oral cavity of a user.
18. (Original) The composition of claim 17, wherein said method provides a bioequivalent absorption of buprenorphine to that of a tablet having an equivalent amount of buprenorphine or a pharmaceutically acceptable salt thereof.
19. (Currently Amended) The method of claim 17, wherein said composition has a local pH of about 3 [[2]] to about 3.5 [[4]].
20. (Original) The method of claim 17, wherein said film dosage composition is administered to the user through buccal administration, sublingual administration, and combinations thereof.
21. (Original) The method of claim 17, wherein said film dosage composition remains in the oral cavity of the user for a period of at least 1 minute.
22. (Original) The method of claim 17, wherein said film dosage composition remains in the oral cavity of the user for a period of between about 1 and 1.5 minutes.

23. (Original) The method of claim 17, wherein said film dosage composition remains in the oral cavity of the user for a period of up to 3 minutes.
24. (Currently Amended) A process of forming a film dosage composition comprising the steps of:
    a. casting a film-forming composition, said film-forming composition comprising:
        i. A polymeric carrier matrix;
        ii. A therapeutically effective amount of buprenorphine or a pharmaceutically acceptable salt thereof;
        iii. A therapeutically effective amount of naloxone or a pharmaceutically acceptable salt thereof; and
        iv. A buffer in an amount to provide a local pH of said composition of a value sufficient to optimize absorption of said buprenorphine and also sufficient to inhibit absorption of said naloxone; and
    b. drying said film-forming composition to form a self-supporting film dosage composition.
25. (Currently Amended) The process of claim 24, wherein said composition has a local pH of about 2 to about 3.5 [[4]].
26. (Currently Amended) A film dosage composition comprising a therapeutically sufficient amount of buprenorphine or a pharmaceutically acceptable salt thereof and a therapeutically sufficient amount of naloxone or a pharmaceutically acceptable salt thereof, said film dosage composition having a bioequivalent release profile as a tablet containing about 2 times the amount of buprenorphine or a pharmaceutically acceptable salt thereof, and wherein said composition provides a local pH of from about 2 to about 3.5.
27. (Original) An orally dissolving film formulation comprising buprenorphine and naloxone, wherein said formulation provides an in vivo plasma profile having a Cmax of between about 0.624 ng/ml and about 5.638 ng/ml for buprenorphine and an in vivo plasma profile having a Cmax of between about 41.04 pg/ml to about 323.75 pg/ml for naloxone.

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