

**MAIL STOP AF
AMENDMENT AFTER FINAL
EXPEDITED PROCESSING**

PATENT
Customer No. 6449
Application No. 14/308,279

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Roberto VILLA <i>et al.</i>)
)
Application No.: 14/308,279) Group Art Unit: 1615
)
Filed: June 18, 2014) Examiner: Susan T. Tran
)
For: CONTROLLED RELEASE AND) Confirmation No.: 9778
TASTE MASKING ORAL)
PHARMACEUTICAL)
COMPOSITIONS)

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

AMENDMENT AFTER FINAL

Sir or Madam:

This paper is being submitted as a response to the Office Action dated 11 December 2015. This Response is timely submitted before the 11 March 2016 due date. Although the Applicants do not believe any additional fees are required, the Commissioner is authorized to charge any additional fees, including extension fees or other relief, which may be required, or credit any overpayment to Deposit Account No. 02-2135.

Amendments to the Claims begin on page 2.

Remarks begin on page 7.

AMENDMENTS TO THE CLAIMS

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

Listing of Claims

1. (Currently Amended) A controlled release oral pharmaceutical composition comprising:
 - (i) budesonide in an amount effective to treat intestinal inflammatory disease;
 - (ii) a macroscopically homogenous structure comprising:
 - (a) at least one lipophilic compound and
 - (b) at least one hydrophilic compound,wherein the macroscopically homogenous structure controls the release of the budesonide; and
 - (iii) a gastro-resistant coating on the macroscopically homogenous structure that prevents release of budesonide in the stomach,
wherein the macroscopically homogenous structure is a tablet.
2. (Canceled)
3. (Original) The controlled release oral pharmaceutical composition according to claim 1, wherein the gastro-resistant coating is at least one compound selected from the group consisting of methacrylic acid polymers and cellulose derivatives.
4. (Original) The controlled release oral pharmaceutical composition according to claim 1, wherein the at least one hydrophilic compound is selected from the group consisting of an acrylic or methacrylic acid polymer or copolymer, an alkylvinyl polymer, a hydroxyalkyl cellulose, a carboxyalkyl cellulose, a polysaccharide, dextrin, pectin, starch, a natural or synthetic gum, and alginic acid.

5. (Original) The controlled release oral pharmaceutical composition according to claim 1, wherein the at least one hydrophilic compound is a hydroxyalkyl cellulose or a carboxyalkyl cellulose.
6. (Previously Presented) The controlled release oral pharmaceutical composition according to claim 3, wherein the at least one hydrophilic compound is a hydroxyalkyl cellulose.
7. (Original) The controlled release oral pharmaceutical composition according to claim 1, further comprising at least one amphiphilic compound.
8. (Currently amended) The controlled release oral pharmaceutical composition according to claim 7, wherein the at least one ~~[[amphiliphile]]~~ amphiphilic compound is selected from the group consisting of lecithin, phosphatidylcholine, phosphatidylethanolamine, ceramide, and a glycol alkyl ether.
9. (Original) The controlled release oral pharmaceutical composition according to claim 7, wherein the at least one amphiphilic compound is lecithin.
10. (Original) The controlled release oral pharmaceutical composition according to claim 1, wherein the at least one lipophilic compound is selected from the group consisting of an unsaturated or hydrogenated alcohol or fatty acid, salt, ester, or amide thereof, a fatty acids mono-, di- or triglyceride, or a polyethoxylated derivative thereof, a wax, ceramide, and a cholesterol derivative.
11. (Original) The controlled release oral pharmaceutical composition according to claim 1, wherein the at least one lipophilic compound is stearic acid.
12. (Original) The controlled release oral pharmaceutical composition according to claim 1, further comprising at least one compound selected from the group consisting of a chitosan, a polyacrylamide, a natural or synthetic gum, and an acrylic acid polymer.

13. (Currently Amended) A controlled release oral pharmaceutical composition comprising:
- (i) budesonide in an amount effective to treat intestinal inflammatory disease;
 - (ii) a macroscopically homogenous structure comprising:
 - (a) at least one amphiphilic compound and
 - (b) at least one hydrophilic compound,wherein the macroscopically homogenous structure controls the release of the budesonide; and
 - (iii) a gastro-resistant coating on the macroscopically homogenous structure that prevents release of budesonide in the stomach,
wherein the macroscopically homogenous structure is a tablet.
14. (Canceled)
15. (Original) The controlled release oral pharmaceutical composition according to claim 13, wherein the gastro-resistant coating is at least one compound selected from the group consisting of methacrylic acid polymers and cellulose derivatives.
16. (Original) The controlled release oral pharmaceutical composition according to claim 13, wherein the at least one hydrophilic compound is selected from the group consisting of an acrylic or methacrylic acid polymer or copolymer, an alkylvinyl polymer, a hydroxyalkyl cellulose, a carboxyalkyl cellulose, a polysaccharide, dextrin, pectin, starch, a natural or synthetic gum, and alginic acid.
17. (Original) The controlled release oral pharmaceutical composition according to claim 13, wherein the at least one hydrophilic compound is a hydroxyalkyl cellulose or a carboxyalkyl cellulose.
18. (Previously Presented) The controlled release oral pharmaceutical composition according to claim 13, wherein the at least one hydrophilic compound is a hydroxyalkyl cellulose.

19. (Original) The controlled release oral pharmaceutical composition according to claim 13, wherein the at least one amphiphilic compound is selected from the group consisting of lecithin, phosphatidylcholine, phosphatidylethanolamine, ceramide, and a glycol alkyl ether.
20. (Original) The controlled release oral pharmaceutical composition according to claim 13, wherein the at least one amphiphilic compound is lecithin.
21. (Original) The controlled release oral pharmaceutical composition according to claim 13, further comprising at least one lipophilic compound selected from the group consisting of an unsaturated or hydrogenated alcohol or fatty acid, salt, ester, or amide thereof, a fatty acids mono-, di- or triglyceride, or a polyethoxylated derivative thereof, a wax, ceramide, and a cholesterol derivative.
22. (Original) The controlled release oral pharmaceutical composition according to claim 21, wherein the at least one lipophilic compound is stearic acid.
23. (Original) The controlled release oral pharmaceutical composition according to claim 13, further comprising at least one compound selected from the group consisting of a chitosan, a polyacrylamide, a natural or synthetic gum, and an acrylic acid polymer.
24. (Currently Amended) A controlled release oral pharmaceutical composition comprising:
 - (i) budesonide in an amount effective to treat intestinal inflammatory disease;
 - (ii) a macroscopically homogenous structure comprising:
 - (a) budesonide;
 - (b) at least one amphiphilic compound;
 - (c) at least one lipophilic compound; and
 - (d) at least one hydrophilic compound,wherein the macroscopically homogenous structure controls the release of the budesonide; and

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