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 *et al.*

Application No.: 14/308,279

Filed: June 18, 2014

For: CONTROLLED RELEASE AND TASTE MASKING ORAL PHARMACEUTICAL COMPOSITIONS

Group Art Unit: 1615

Examiner: Susan T. Tran

Confirmation No.: 9778

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

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 [[amphiliphilc]] 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

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.