IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	: 13/617,138
Applicant	: Roberto VILLA *et al.*
Filed	: 14 September 2012
TC/A.U.	: 1615
Examiner	: Susan T. Tran
Docket No.	: 3850-125
Customer No.	: 06449
Confirmation No.	: 7811

AMENDMENT

MAIL STOP AMENDMENT
Director of the United States Patent
and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In response to the Office Action dated 16 November 2012, please amend this application as follows:

Amendments to the Claims begin on page 2.

Remarks begin on page 5.

Exhibit 1052

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:

(1) a tablet core comprising:

a) budesonide in an amount effective for treatment of inflammatory bowel disease in the gastrointestinal tract,

b) a lipophilic excipient;

c) an amphiphilic excipient;

d) a hydrogel-forming hydrophilic excipient other than a gum; and

(2) a coating on said tablet core, said coating comprising a gastro-resistant film.

2. (Currently Amended) ~~The composition of~~ A controlled release oral pharmaceutical composition according to claim 1, ~~comprising~~ wherein said controlled release oral pharmaceutical composition comprises 9 mg of budesonide.

3. (New) A controlled release oral pharmaceutical composition according to claim 1, wherein said hydrogel-forming hydrophilic excipient comprises hydroxypropyl cellulose.

4. (New) A controlled release oral pharmaceutical composition according to claim 2, wherein said hydrogel-forming hydrophilic excipient comprises hydroxypropyl cellulose.

5. (New) A controlled release oral pharmaceutical composition according to claim 1, wherein said gastro-resistant film comprises at least one methacrylic acid polymer or copolymer.

6. (New) A controlled release oral pharmaceutical composition according to claim 5, wherein said hydrogel-forming hydrophilic excipient comprises hydroxypropyl cellulose.

7. (New) A controlled release oral pharmaceutical composition according to claim 1, wherein said lipophilic excipient and said amphiphilic excipient are present in said controlled release oral pharmaceutical composition in a ratio of about 1 to 1 by weight.

8. (New) A controlled release oral pharmaceutical composition according to claim 7, wherein said hydrogel-forming hydrophilic excipient comprises hydroxypropyl cellulose.

9. (New) A controlled release oral pharmaceutical composition according to claim 1, wherein said lipophilic excipient comprises stearic acid.

10. (New) A controlled release oral pharmaceutical composition according to claim 9, wherein said hydrogel-forming hydrophilic excipient comprises hydroxypropyl cellulose.

11. (New) A controlled release oral pharmaceutical composition according to claim 1, wherein said amphiphilic excipient comprises lecithin.

12. (New) A controlled release oral pharmaceutical composition according to claim 11, wherein said hydrogel-forming hydrophilic excipient comprises hydroxypropyl cellulose.

REMARKS

Amendments

Claim 1 has been amended to specify that the hydrogel-forming hydrophilic excipient is not a gum. The as-filed specification discloses at paragraph 36 that the hydrophilic excipient can comprise hydrogel compounds, including natural or synthetic gums. As such, there is written description support for amending claim 1 to recite that the hydrogel-forming hydrophilic excipient comprising the presently claimed controlled release oral pharmaceutical compositions is other than a gum. *In re Johnson*, 558 F.2d 1008 (C.C.P.A. 1977).

New claims 3, 4, 6, 8, 10 and 12 have been added to specify that the hydrogel-forming hydrophilic excipient comprises hydroxypropyl cellulose. Support for these claims can be found in the as-filed specification at least in Example 1 (paragraphs [0047] to [0051]) and Example 2 (paragraphs [0052] to [0055]).

New claim 5 has been added to specify that the gastro resistant film comprises at least one methacrylic acid polymer or copolymer. Support for this claim can be found in the as-filed specification at least in Example 1 (paragraphs [0047] to [0051]) and Example 2 (paragraphs [0052] to [0055]).

New claim 7 has been added to specify that the lipophilic excipient and amphiphilic excipient are in a 1:1 ratio. Support for this claim can be found in the as-filed specification at least in Example 1 (paragraphs [0047] to [0051]) and Example 2 (paragraphs [0052] to [0055]).

New claim 9 has been added to specify that the lipophilic excipient is stearic acid. Support for this claim can be found in the as-filed specification at least in Example 1 (paragraphs [0047] to [0051]) and Example 2 (paragraphs [0052] to [0055]).

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