

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 12/811,737  
Applicant : Federico STROPPOLO, *et al.*  
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Director of the United States Patent  
and Trademark Office  
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**AMENDMENT AND RESPONSE UNDER 37 C.F.R. §1.111**

This paper responds to the Office Action mailed February 14, 2012, and is timely  
filed within three months.

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

**Remarks** begin on page 4 of this paper.

**AMENDMENTS TO THE CLAIMS**

The following listing of claims replaces and supersedes all previous listings.

**Listing of Claims:**

1. (Currently Amended) An orally ~~Orally~~ disintegrating ~~tablets~~ tablet with speckled appearance comprising colored granules of a water-soluble sugar in admixture with a pharmaceutically acceptable carrier.
2. (Currently Amended) The orally ~~Orally~~ disintegrating ~~tablets~~ tablet according to claim 1 wherein the water-soluble sugar is selected from the group consisting of sucrose and polyalcohols.
3. (Currently Amended) The orally ~~Orally~~ disintegrating ~~tablets~~ tablet according to claim 2 wherein the water-soluble sugar is selected from the group consisting of sucrose, sorbitol, mannitol, xylitol, and fructose.
4. (Currently Amended) The orally ~~Orally~~ disintegrating ~~tablets~~ tablet according to claim 3 wherein the water-soluble sugar is mannitol.
5. (Currently Amended) The orally ~~Orally~~ disintegrating ~~tablets~~ tablet according to claim 1 wherein the colored granules have a particle size from about 10  $\mu\text{m}$  to about 1200  $\mu\text{m}$ .

6. (Currently Amended) The orally Orally disintegrating tablets tablet according to claim 5 wherein the colored granules have a particle size from about 200  $\mu\text{m}$  to about 800  $\mu\text{m}$ .

7. (Currently Amended) The orally Orally disintegrating tablets tablet according to claim 6 wherein the colored granules have a particle size from about 300  $\mu\text{m}$  to about 500  $\mu\text{m}$ .

8. (Currently Amended) The orally Orally disintegrating tablets tablet according to claim 1 wherein the colored granules are present in an amount from about 0.1% w/w to about 50% w/w per tablet.

9. (Currently Amended) The orally Orally disintegrating tablets tablet according to claim 1 wherein the colored granules are present in an amount from about 1% w/w to about 30% w/w per tablet.

10. (Withdrawn—Currently Amended) A method for the identification of an orally disintegrating tablets tablet comprising the use of an orally disintegrating tablet with speckled appearance according to claim 1.

11. (Withdrawn) A method according to claim 10 wherein the orally disintegrating tablet is scored and embossed with one or more symbols, letters, numbers or combination thereof.

### **REMARKS**

The Office Action mailed February 14, 2012, has been received and carefully reviewed. The preceding amendments and the following remarks form a full and complete response thereto. In the Office Action, claims 1-9 are pending and stand rejected. Claims 10-11 have been withdrawn. Claims 1-10 are currently amended. Support for these amendments can be found, *inter alia*, in the original claims and the specification. No new matter has been added. Reconsideration of the outstanding rejections is respectfully requested in view of the above amendments and the following remarks.

#### **Objection to Claims 1-9 for Informalities**

Claims 1-9 were objected to because of informalities. More specifically, claims 1-9 were objected to for failing to recite an article at the beginning of each claim. Claims 1-9 have been amended such that an article, either “an” or “the” precedes each claim. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Claim 9 was objected to for reciting an incomplete unit. Per the Examiner’s suggestion, claim 9 has been amended to recite that “the colored granules are present in an amount from about 1% w/w to about 30% w/w per tablet.” Accordingly, Applicants respectfully request that the rejection be withdrawn.

**35 U.S.C. § 102(b)**

Claims 1-4 and 8 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Publication No. 2003/0180357 to Martino, et al. (“Martino”). Applicants respectfully submit that Martino does not describe each and every element of independent claim 1. Specifically, Applicants submit that Martino fails to describe “colored granules of a water-soluble sugar.”

In Martino, mannitol and a dye are blended in a high-shear mixer. *See* Martino, paragraph [0085]. The result of the process in Martino is a “homogenous mixture of mannitol and dye,” not colored granules of a water-soluble sugar. *Id.* Furthermore, the speckled appearance of the tablet is due to the coating with an aqueous coating composition comprising gellan gum. *See* Martino, paragraph [0013].

In contrast, the present invention does not require a coating for a speckled appearance, but rather is speckled due to the presence of “colored granules of a water-soluble sugar.” As described in the specification, the production of “colored granules of a water-soluble sugar” involves “granulation of the water-soluble sugar with an aqueous suspension or solution of the coloring agent in a suitable fluid bed granulator.” Thus, it is clear both from the claim language and the specification of the present invention, that the granules of colored water-soluble sugar are distinct from Martino’s description of a mixture of an uncolored water-soluble sugar and a dye. Accordingly, Applicants submit that Martino does not describe each and every element of claim 1. Since claims 2-4 and 8 depend on claim 1 and thus include the same claim element, Applicants respectfully request that the rejection be withdrawn.

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