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(12) **United States Patent**
Dalvi et al.(10) **Patent No.:** **US 9,415,008 B2**
(45) **Date of Patent:** ***Aug. 16, 2016**(54) **DRY POWDER INHALER**(71) Applicant: **Teva Branded Pharmaceutical Products R&D, Inc.**, Frazer, PA (US)(72) Inventors: **Mukul Dalvi**, Weston, FL (US); **Seah Kee Tee**, Weston, FL (US)(73) Assignee: **Teva Branded Pharmaceutical Products R&D, Inc.**, Frazer, PA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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(51) **Int. Cl.****A61K 31/56** (2006.01)**A61M 15/00** (2006.01)**A61K 9/00** (2006.01)**A61K 31/137** (2006.01)(52) **U.S. Cl.**CPC **A61K 9/0075** (2013.01); **A61K 31/137** (2013.01); **A61K 31/56** (2013.01); **A61M 15/0005** (2014.02); **A61M 15/0021** (2014.02); **A61M 2202/064** (2013.01)(58) **Field of Classification Search**CPC **A61K 31/569**; **A61K 31/137**; **A61K 31/57**USPC **514/171**; **128/203.15**

See application file for complete search history.

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Entire patent prosecution history of U.S. Appl. No. 14/507,210, filed Oct. 6, 2014, entitled, "Dry Powder Inhaler," now U.S. Pat. No. 9,066,957, issued Jun. 30, 2015.

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This invention provides a dry powder inhaler comprising: a dry powder medicament comprising fluticasone propionate, salmeterol xinafoate and a lactose carrier; wherein, the delivered dose of fluticasone propionate per actuation is less than 100 µg; and wherein the dose provides a baseline-adjusted FEV₁ in a patient of more than 150 mL within 30 minutes of receiving the dose. A method of treating a patient includes administering to a patient a dry powder medicament having fluticasone propionate, salmeterol xinafoate and a lactose carrier; wherein, the delivered dose of fluticasone propionate per actuation is less than 100 µg; and wherein the dose provides a baseline-adjusted FEV₁ in a patient of more than 150 mL within 30 minutes of receiving the dose.

20 Claims, 11 Drawing Sheets