PATENT
2801-0162P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#38/F
#KD
9.26.02

Applicant:	Robert K. SCHULTZ et al.	Conf.:	Unknown
Appl. No.:	08/455,280	Group:	1616
Filed:	May 31, 1995	Examiner:	J. Dees
For:	SUSPENSION AEROSOL FORMULATIONS		

AMENDMENT

Assistant Commissioner for Patents
Washington, DC 20231

30 July 2002

Sir:

The following amendments and remarks are respectfully submitted in connection with the above-identified application.

IN THE CLAIMS:

Please cancel claim 109 and 118-121.

The claims have been amended to read as follows:

106. (Amended) The pharmaceutical suspension aerosol formulation of claim 105, wherein the particulate drug comprises a drug selected from the group consisting of formoterol, beclomethasone dipropionate, pirbuterol, albuterol, and pharmaceutically acceptable salts and solvates thereof.

F2

108. (Amended) The pharmaceutical suspension aerosol formulation of claim 105, wherein the drug is formoterol or a pharmaceutically acceptable salt thereof.

F3

116. (Amended) A pharmaceutical aerosol formulation consisting essentially of a particulate drug which is albuterol or a physiologically acceptable salt or solvate thereof and 1,1,1,2-tetrafluoroethane as propellant, which formulation is substantially free of surfactant, the particulate drug being present in a therapeutically effective amount of less than 1.6% w/w relative to the total weight of the formulation and wherein 90% or more of the particles have a diameter of less than 10 microns.

117. (Amended) A canister suitable for delivering a pharmaceutical aerosol formulation for inhalation therapy which comprises a container capable of withstanding the vapor pressure of the propellant used, which container is closed with a metering valve and contains a pharmaceutical aerosol formulation consisting essentially of a particulate drug which is albuterol or a physiologically acceptable salt or solvate thereof and 1,1,1,2-tetrafluoroethane as propellant, which formulation is substantially free of surfactant, the particulate drug being present in a therapeutically effective amount of less than 1.6% w/w relative to

F2

108. (Amended) The pharmaceutical suspension aerosol formulation of claim 105, wherein the drug is formoterol or a pharmaceutically acceptable salt thereof.

F3

116. (Amended) A pharmaceutical aerosol formulation consisting essentially of a particulate drug which is albuterol or a physiologically acceptable salt or solvate thereof and 1,1,1,2-tetrafluoroethane as propellant, which formulation is substantially free of surfactant, the particulate drug being present in a therapeutically effective amount of less than 1.6% w/w relative to the total weight of the formulation and wherein 90% or more of the particles have a diameter of less than 10 microns.

117. (Amended) A canister suitable for delivering a pharmaceutical aerosol formulation for inhalation therapy which comprises a container capable of withstanding the vapor pressure of the propellant used, which container is closed with a metering valve and contains a pharmaceutical aerosol formulation consisting essentially of a particulate drug which is albuterol or a physiologically acceptable salt or solvate thereof and 1,1,1,2-tetrafluoroethane as propellant, which formulation is substantially free of surfactant, the particulate drug being present in a therapeutically effective amount of less than 1.6% w/w relative to

F-3 (cont'd)

the total weight of the formulation and wherein 90% or more of the particles have a diameter of less than 10 microns.

F-4

122. (Amended) A pharmaceutical formulation consisting essentially of (i) one or more particulate drugs, and (ii) 1,1,1,2-tetrafluoroethane as propellant, which formulation is substantially free of surfactant, the particulate drug being present in a therapeutically effective amount less than 1.6% w/w relative to the total weight of the formulation and wherein 90% or more of the particles have a diameter of less than 10 microns, wherein one of the said one or more particulate drugs is a bronchodilator selected from the group consisting of formoterol and pirbuterol or a physiologically acceptable salt thereof.

Please add the following claims:

F-5

123. (New) A pharmaceutical suspension formulation suitable for aerosol administration consisting essentially of:

(i) particulate drug; and

(ii) 1,1,1,2-tetrafluoroethane as propellant,

wherein the formulation is substantially free of surfactant.

124. (New) The pharmaceutical suspension aerosol formulation of claim 123, wherein the drug is albuterol or a pharmaceutically acceptable salt or solvate thereof.

F3 Contd

the total weight of the formulation and wherein 90% or more of the particles have a diameter of less than 10 microns.

F4

122. (Amended) A pharmaceutical formulation consisting essentially of (i) one or more particulate drugs, and (ii) 1,1,1,2-tetrafluoroethane as propellant, which formulation is substantially free of surfactant, the particulate drug being present in a therapeutically effective amount less than 1.6% w/w relative to the total weight of the formulation and wherein 90% or more of the particles have a diameter of less than 10 microns, wherein one of the said one or more particulate drugs is a bronchodilator selected from the group consisting of formoterol and pirbuterol or a physiologically acceptable salt thereof.

Please add the following claims:

F5

123. (New) A pharmaceutical suspension formulation suitable for aerosol administration consisting essentially of:

(i) particulate drug; and

(ii) 1,1,1,2-tetrafluoroethane as propellant,

wherein the formulation is substantially free of surfactant.

124. (New) The pharmaceutical suspension aerosol formulation of claim 123, wherein the drug is albuterol or a pharmaceutically acceptable salt or solvate thereof.

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