1.129(a) + E

3M Attorney Docket No. 47982USA5C
Attorney Docket No. 03196.0019-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Bet
12-14-98

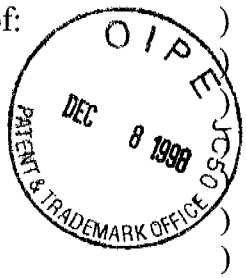
Rule 1.129(a) Submission of:

Robert K. Schultz et al.

Serial No. 08/455,280

Filed: May 31, 1995

For: SUSPENSION AEROSOL FORMULATIONS



Group Art Unit: 1615

Examiner: G. Kishore, Ph.D.

Assistant Commissioner of Patents
Washington, D.C. 20231

Second Submission Under 37 C.F.R. § 1.129(a) and
Request That an Interference Be Declared Under 37 C.F.R. § 1.607

This submission is being made pursuant to 37 C.F.R. § 1.129(a) and 37 C.F.R. § 1.607. The requisite fee under 37 C.F.R. § 1.17(r) and any extension fee under 37 C.F.R. § 1.136(a) are attached. Prior to examination of this submission, and for purposes of declaring an interference, please amend the above-identified application as follows:

12/10/1998 TLUU11 00000029 08455280
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IN THE CLAIMS

Please cancel claims 30, 61-101, and 103-104. Please add the following new claims:

--105. A pharmaceutical suspension formulation suitable for aerosol administration consisting essentially of:

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(i) particulate drug; and

(ii) 1,1,1,2-tetrafluoroethane as propellant, wherein the formulation is further characterized in that it contains no surfactant.

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

107. The pharmaceutical suspension aerosol formulation of claim 105, wherein the particulate drug is micronized.

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

109. The pharmaceutical suspension aerosol formulation of claim 105, wherein the drug is salmeterol or a pharmaceutically acceptable salt or solvate thereof.

110. The pharmaceutical suspension aerosol formulation of claim 105, wherein the drug is albuterol or a pharmaceutically acceptable salt or solvate thereof.

111. The pharmaceutical suspension aerosol formulation of claim 105, wherein the drug is beclomethasone dipropionate or a pharmaceutically acceptable solvate thereof.

112. The pharmaceutical suspension aerosol formulation of claim 105, wherein the drug is pirbuterol or a pharmaceutically acceptable salt or solvate thereof.

113. The pharmaceutical suspension aerosol formulation of claim 110, wherein the drug is albuterol sulfate.

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114. The pharmaceutical suspension aerosol formulation of claim 112, wherein the drug is pirbuterol acetate.

115. An aerosol canister equipped with a metering valve, containing a formulation according to claim 105 in an amount sufficient to provide a plurality of therapeutically effective doses of the drug.

116. A pharmaceutical aerosol formulation consisting essentially of a particulate medicament which is salbutamol or a physiologically acceptable salt or solvate thereof and 1,1,1,2-tetrafluoroethane as propellant, which formulation contains less than 0.0001% surfactant based upon the weight of medicament, the particulate medicament being present in an amount of 0.005% to 5% w/w relative to the total weight of the formulation and having a particle size of less than 100 microns, with the provisos that when said formulation consists of salbutamol and 1,1,1,2-tetrafluoroethane in a weight ratio of 0.05:18, said salbutamol is present in the form of a physiologically acceptable salt and when said formulation consists of salbutamol or salbutamol sulphate and 1,1,1,2-tetrafluoroethane the weight to weight ratio of medicament to propellant is other than 69:7900 or 0.866%.

117. 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 medicament which is salbutamol or a physiologically acceptable salt or solvate thereof and 1,1,1,2-tetrafluoroethane as propellant, which formulation contains less than 0.0001% w/w surfactant based upon the weight of

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medicament, the particulate medicament being present in an amount of from 0.005 to 5% w/w relative to the total weight of the formulation and having a particle size of less than 100 microns, and with the provisos that when said formulation consists of salbutamol and 1,1,1,2-tetrafluoroethane in a weight ratio of 0.05:18, said salbutamol is present in the form of a physiologically acceptable salt and when said formulation consists of salbutamol or salbutamol sulphate and 1,1,1,2-tetrafluoroethane the weight to weight ratio of medicament to propellant is other than 69:7900 or 0.866%.

118. A pharmaceutical aerosol formulation consisting essentially of particulate medicament which is fluticasone propionate or a physiologically acceptable solvate thereof, and 1,1,1,2-tetrafluoroethane as propellant, which formulation contains less than 0.0001% w/w surfactant based upon the weight of medicament, the particulate medicament being present in an amount of from 0.005% to 5% w/w relative to the total weight of the formulation and having a particle size of less than 100 microns.

119. A canister suitable for delivering a pharmaceutical aerosol formulation 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 medicament which is fluticasone propionate or a physiologically acceptable solvate thereof and 1,1,1,2-tetrafluoroethane as propellant, which formulation contains less than 0.0001% w/w surfactant based upon the weight of medicament, the particulate medicament being present in an amount of from 0.005 to 5% w/w relative to the total weight of the formulation and having a particle size of less than 100 microns.

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120. A pharmaceutical aerosol formulation consisting essentially of a particulate medicament which is salmeterol or a physiologically acceptable salt or solvate thereof and 1,1,1,2-tetrafluoroethane as propellant, which formulation contains less than 0.0001% w/w surfactant based upon the weight of medicament, the particulate medicament being present in an amount of from 0.005 to 5% w/w relative to the total weight of the formulation and having a particle size of less than 100 microns.

121. 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 medicament which is salmeterol or a physiologically acceptable salt or solvate thereof and 1,1,1,2-tetrafluoroethane as propellant, which formulation contains less than 0.0001% w/w surfactant based upon the weight of medicament, the particulate medicament being present in an amount of from 0.005 to 5% w/w relative to the total weight of the formulation and having a particle size of less than 100 microns.

122. A pharmaceutical formulation consisting essentially of (i) one or more particulate medicaments, and (ii) 1,1,1,2-tetrafluoroethane as propellant, which formulation contains less than 0.0001% w/w surfactant based upon the weight of medicament, the particulate medicament being present in an amount from 0.005 to 5% w/w relative to the total weight of the formulation and having a particle size of less than 100 microns, wherein one of the said one or more medicaments is a bronchodilator selected from the group consisting of ephedrine, adrenaline, fenoterol, formoterol, isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine,

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