IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application No. 10/616,709

Applicant: Desai et al.

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Examiner: Roy R. Teller

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY TO OFFICE ACTION

Sir:

In reply to the Office Action dated March 13, 2007, please enter the following amendments and consider the following remarks.

The claims pending in this application are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 11 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions, and listings, of claims in the application.

1. (Currently Amended) A sterile pharmaceutical composition ~~for parenteral administration~~ of propofol stored in a container, said composition comprising propofol[[,]] and less than about 10% by weight solvent for propofol, said container in which said composition is stored comprising a closure for said container, ~~wherein said composition is stored in a container having a closure~~ wherein said closure is inert to propofol.

2. (Original) The composition of claim 1, wherein said composition further comprises an aqueous phase and protein.

3. (Original) The sterile pharmaceutical composition of claim 2, wherein the protein is albumin.

4. (Original) The sterile pharmaceutical composition of claim 3, wherein the albumin is present in an amount of from about 0.01% to about 5% by weight of the composition.

5. (Original) The sterile pharmaceutical composition of claim 2, wherein the aqueous phase comprises water of injection and a pH modifier.

6. (Original) The sterile pharmaceutical composition of claim 2, wherein the composition comprises a tonicity agent.

7. (Original) The sterile pharmaceutical composition of claim 3, wherein the pH modifier is sodium hydroxide.

8. (Original) The sterile pharmaceutical composition of claim 6, wherein the tonicity agent is glycerin.

9. (Original) The sterile pharmaceutical composition of claim 2, wherein said composition further comprises surfactant.

10. (Original) The sterile pharmaceutical composition of claim 1, wherein said composition further comprises a solvent for propofol.

11. (Original) The sterile pharmaceutical composition of claim 10 wherein the solvent is a water-immiscible solvent.

12. (Original) The sterile pharmaceutical composition of claim 11, wherein the water-immiscible solvent is selected from the group consisting of soybean, safflower, cottonseed, corn, coconut, sunflower, arachis, castor sesame, orange, limonene or olive oil, an ester of a medium or long-chain fatty acid, a chemically modified or manufactured palmitate, glyceral ester or polyoxyl, hydrogenated castor oil, a marine oil, fractionated oils, and mixtures thereof.

13. (Original) The sterile pharmaceutical composition of claim 12, wherein the water-immiscible solvent is soybean oil.

14. (Original) The sterile pharmaceutical composition of claim 10, wherein the solvent is selected from the group consisting of chloroform, methylene chloride, ethyl acetate, ethanol, tetrahydrofuran, dioxane, acetonitrile, acetone, dimethyl sulfoxide, dimethyl formamide, methyl pyrrolidinone, C1-C20 alcohols, C2-C20 esters, C3-C20 ketones, polyethylene glycols, aliphatic hydrocarbons, aromatic hydrocarbons, halogenated hydrocarbons and combinations thereof.

15. (Original) The sterile pharmaceutical composition of claim 9, wherein the surfactant is selected from the group consisting of phosphatides, synthetic phospholipids, natural phospholipids, lecithins, ethoxylated ethers and esters, tocopherol polyethylene glycol stearate, polypropylene-polyethylene block co-polymers, polyvinyl pyrrolidone, and polyvinylalcohol and combinations thereof.

16. (Original) The sterile pharmaceutical composition of claim 15, wherein the surfactant is selected from the group consisting of egg phosphatides, soya phosphatides, egg lecithins, soya lecithins, and compositions thereof.

17. (Original) The sterile pharmaceutical composition of claim 16, wherein the surfactant is egg lecithin.

18. (Original) The sterile pharmaceutical composition of claim 1, wherein said closure is coated with a material inert to propofol.

19. (Original) The sterile pharmaceutical composition of claim 1, wherein said closure is comprised of a material that is itself inert to propofol.

20. (Original) The sterile pharmaceutical composition of claim 19, wherein the material inert to propofol is selected from the group consisting of a fluoropolymer, silicone, and mixtures thereof.

21. (Original) The sterile pharmaceutical composition of claim 19, wherein said material is selected from the group consisting of bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, non-rubber, metal, and mixtures thereof.

22. (Original) The sterile pharmaceutical composition of claim 19, wherein the material is selected from the group consisting of bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, and mixtures thereof.

23. (Original) The sterile pharmaceutical composition of claim 1, wherein said closure comprises bromobutyl rubber coated with a fluoropolymer.

24. (Original) The sterile pharmaceutical composition of claim 1, wherein said closure comprises siliconized bromobutyl rubber.

25. (Original) The sterile pharmaceutical composition of claim 1, wherein said closure comprises a non-rubber, or metal.

26. (Original) The sterile pharmaceutical composition of claim 1, wherein said closure comprises chlorobutyl rubber coated with a fluoropolymer.

27. (Original) The sterile pharmaceutical composition of claim 1, wherein said closure comprises siliconized chlorobutyl rubber.

28. (Original) The sterile pharmaceutical composition of claim 1, wherein the composition comprises propofol in an amount of from about 0.1% to about 10% by weight of the composition, soybean oil in an amount of from about 0.5% to about 6% by weight of the composition, egg lecithin in an amount of from about 0.1% to about 5% by weight of the composition and human serum albumin in an amount of from about 0.1% to about 5% of the composition.

29. (Currently Amended) A sterile pharmaceutical composition of propofol stored in a container comprising ~~in the form of~~ an oil-in-water emulsion for parenteral administration of propofol, said composition comprising an oil phase comprising propofol[[,]] and less than about 10% by weight solvent for propofol and an aqueous phase comprising water for injection, ~~and wherein~~ the composition further comprising ~~includes~~ a stabilizing layer for the oil phase, said stabilizing layer comprising a surfactant and a protein, said container in which the composition is stored comprising a closure for the ~~wherein said composition is stored in a~~ container, ~~having a closure~~ wherein said closure is inert to propofol.

30. (Original) The composition of claim 29, wherein said protein is selected from the group consisting of albumins, globulins, immunoglobulins, lipoproteins, caseins, insulins, hemoglobins, lysozymes, alpha-2-macroglobulin, fibronectins, vitronectins, fibrinogens, lipases, peptides, enzymes, antibodies and combinations thereof.

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