

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Desai	Art Unit: 1654
Application No.: 10/616,709	Examiner: Roy R. Teller
Filed: 10 Jul 2003	Confirmation No.: 2620
Title: Propofol Formulations With Non-Reactive Container Closures	
Attorney Docket No.: APP01_005_US	

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

RESPONSE UNDER 37 CFR 1.114

Dear Sir:

This communication responds to the Office Action mailed on March 23, 2010. Applicants respectfully request that the Examiner reconsider the rejections in view of the following amendments and remarks.

Amendments to the Claims are reflected in the listing of claims which begins on page 2.

Remarks begin on page 16.

IN THE CLAIMS:

In accord with Rule § 1.121, a complete claim listing is presented below, including appropriate status identifiers. The changes in amended claims are shown by strikethrough or double brackets for deleted material, and by underlining for added material.

1. (Currently Amended) A sterile pharmaceutical composition of propofol in a container, comprising:
 - a container which includes a closure ~~inert to propofol~~ and a composition in the container,
 - the composition in the container comprising from 0.5% to 10% by weight propofol and less than ~~about~~ 10% by weight solvent for propofol, and
 - when the composition in the container sealed with the closure is agitated at a frequency of 300-400 cycles/minute for 16 hours at room temperature, the composition maintains a propofol concentration (w/v) measured by HPLC that is at least 93% of the starting concentration (w/v) of the propofol.
2. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, the composition further comprising an aqueous phase and protein.
3. (Previously presented) The sterile pharmaceutical composition in a container according to claim 2, wherein the protein is albumin.
4. (Previously presented) The sterile pharmaceutical composition in a container according to claim 3, wherein the albumin is present in an amount of from about 0.01% to about 5% by weight of the composition.
5. (Previously presented) The sterile pharmaceutical composition in a container according to claim 2, wherein the aqueous phase comprises water for injection and a pH modifier.

6. (Previously presented) The sterile pharmaceutical composition in a container according to claim 2, wherein the composition comprises a tonicity agent.
7. (Previously presented) The sterile pharmaceutical composition in a container according to claim 3, wherein the pH modifier is sodium hydroxide.
8. (Previously presented) The sterile pharmaceutical composition in a container according to claim 6, wherein the tonicity agent is glycerin.
9. (Previously presented) The sterile pharmaceutical composition in a container according to claim 2, wherein the composition further comprises a surfactant.
10. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the composition further comprises a solvent for propofol.
11. (Previously presented) The sterile pharmaceutical composition in a container according to claim 10 wherein the solvent is a water-immiscible solvent.
12. (Previously presented) The sterile pharmaceutical composition in a container according to 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, glycerol ester or polyoxyl, hydrogenated castor oil, a marine oil, fractionated oils, and mixtures thereof.
13. (Previously presented) The sterile pharmaceutical composition in a container according to claim 12, wherein the water-immiscible solvent is soybean oil.
14. (Previously presented) The sterile pharmaceutical composition in a container according to 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. (Previously presented) The sterile pharmaceutical composition in a container according to 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 copolymers, polyvinyl pyrrolidone, and polyvinylalcohol and combinations thereof.

16. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 15, wherein the surfactant is selected from the group consisting of egg phosphatides, soya phosphatides, egg lecithins, soya lecithins, and ~~compositions~~ combinations thereof.

17. (Previously presented) The sterile pharmaceutical composition in a container according to claim 16, wherein the surfactant is egg lecithin.

18. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure is coated with a material inert to propofol.

19. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure ~~is comprised~~ consists essentially of a material that is itself inert to propofol.

20. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 19, wherein the closure material ~~inert to propofol~~ is selected from the group consisting of a fluoropolymer, silicone, and mixtures thereof.

21. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 19, wherein the closure material is a non-rubber selected from the group consisting of ~~bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, non-rubber,~~ metal, plastics, and mixtures thereof.

22. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~19~~ 1, wherein the closure comprises a material is selected from the group consisting of bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, and mixtures thereof.

23. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure comprises bromobutyl rubber coated with a fluoropolymer.

24. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure comprises siliconized bromobutyl rubber.

25. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure comprises a non-rubber, ~~or~~ selected from the group consisting of metal, plastics, and mixtures thereof.

26. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure comprises chlorobutyl rubber coated with a fluoropolymer.

27. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure comprises siliconized chlorobutyl rubber.

28. (Currently Amended) The sterile pharmaceutical composition in a container according to 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

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