

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| 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.: FKA01_005_US | |

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

RESPONSE UNDER 37 CFR 1.111

Dear Sir:

This communication responds to the Office Action mailed on December 10, 2012. 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 15.

Bass and Spangenberg
v.
Fresenius Kabi USA, LLC
U.S. Patent No. 8,476,010

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 and a composition in the container, and the composition in the container comprising from 0.5% to 10% by weight propofol and less than 10% by weight solvent for propofol,
 - where 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;
 - where the closure is selected from the group consisting of
 - siliconized bromobutyl rubber,
 - a non-rubber selected from the group consisting of metal, plastics, and mixtures thereof, and
 - siliconized chlorobutyl rubber.
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. (Previously presented) 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 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. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure consists essentially of a material that is itself inert to propofol.
20. (Cancelled)

21. (Previously presented) 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 metal, plastics, and mixtures thereof.

22-23. (Cancelled)

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

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

26. (Cancelled)

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

28. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the composition comprises 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 in a container, comprising:

a container which includes a closure and an oil-in-water emulsion for parenteral administration of propofol in the container,

the emulsion comprising an oil phase comprising propofol and a solvent for propofol, and an aqueous phase comprising water for injection,

the emulsion comprising less than 10% by weight of the solvent,

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