WHAT IS CLAIMED IS

1. Use of a sterile injectable solution in the manufacture of a medicament for the treatment of abdominal adiposity, regional adiposity or exophthalmos due to thyroid eye disease which solution is reconstituted by dissolving a lyophilized composition comprising salmeterol or a pharmaceutically acceptable salt thereof and a bulking agent in which said salmeterol or pharmaceutically acceptable salt thereof comprises in an amount of 0.00001 % to 0.1% of the dry weight of the lyophilized composition.

2. Use according to claim 1 wherein the lyophilized salmeterol or pharmaceutically acceptable salt thereof is in a crystalline phase, an amorphous phase, a semi-crystalline phase, a semi-amorphous phase, or a mixture thereof.

3. Use according to any of claims 1-2 comprising salmeterol xinafoate.

4. Use according to any of claims 1-3 wherein the lyophilized salmeterol or pharmaceutically acceptable salt thereof is present in an amount of 0.00034 % to 0.00046 % by weight of the total combined dry weight of the lyophilized composition.

5. Use according to any of claims 3-4 wherein the lyophilized salmeterol or pharmaceutically acceptable salt thereof is present in an amount of 100 nanograms/gram to 250 micrograms/gram.

6. Use according to any of claims 3-4 wherein the lyophilized salmeterol or pharmaceutically acceptable salt thereof is present in an amount of 225 nanograms/gram to 250 micrograms/gram.

7. Use according to any of claims 1-6 wherein the bulking agent is selected from the group consisting of lactose, mannitol, dextrose, sucrose, and combinations thereof.

8. Use according to claim 7 wherein the bulking agent is lactose monohydrate.

9. Use according to any of claims 1-8 wherein the non-ionic surfactant if present is in an amount of 1 % to 10 % by weight of the total combined dry weight of the lyophilized composition and the bulking agent is present in an amount of at least 90 % by weight of the total combined dry weight of the lyophilized composition, and the lyophilized salmeterol or pharmaceutically acceptable salt

thereof is present in an amount of 0.00001 % to 0.1 % by weight of the total combined dry weight of the lyophilized composition.

10. Use according to any of claims 1-9 wherein the composition is suitable, upon reconstitution with an aqueous solution, for subcutaneous, peri-orbital, intra-orbital, or intramuscular administration.

11. Use according to any of claims 1-10 wherein the composition is suitable, upon reconstitution with an aqueous solution, for subcutaneous administration.

12. Use according to any of claims 1-11 wherein the composition contains less than 2 % water by weight of the total combined dry weight of the lyophilized composition.

13. Use of a pharmaceutical composition of claim 1 in the manufacture of a medicament for the treatment of abdominal adiposity.

14. Use according to claim 13, further comprising a pharmaceutically acceptable diluent that is selected from sterile water for injection, sterile saline, or 5% dextrose solution.

15. Use according to any of claims 13-14 wherein the pharmaceutically acceptable diluent is Sterile Water for Injection.

16. Use according to any of claims 13-15 wherein the reconstituted salmeterol or pharmaceutically acceptable salt thereof is present in an amount of 100 nanograms/milliliter to 25 micrograms/milliliter.

17. Use according to any of claims 13-16 wherein the reconstituted salmeterol or pharmaceutically acceptable salt thereof is present in an amount of 4 nanograms/milliliter to 750 nanograms/milliliter.

18. Use according to any of claims 13-17, said composition being formulated for subcutaneous administration by injection.

19. Use according to claim 18 wherein the lyophile is dissolved in a pharmaceutically acceptable diluent to obtain the reconstituted sterile formulation.

20. Use according to claim 19 which is a clear solution.

21. Use according to any of claims 1 to 20 which also comprises a non-ionic surfactant.

22. A method of cosmetic treatment which affects the shape, contour or appearance of the human body which method comprises administering by subcutaneous or other injection to a human a reconstituted formulation comprising sterile salmeterol or pharmaceutically acceptable salt thereof that has been reconstituted from a lyophilized composition that comprised lyophilized salmeterol or a pharmaceutically acceptable salt thereof and a bulking agent, provided that the salmeterol or a pharmaceutically acceptable salt thereof is present in an amount of 0.00001 % to 0.1 % by weight of the total combined dry weight of the lyophilized composition.

23. A cosmetic method of claim 22 wherein the reconstituted sterile formulation comprising salmeterol or pharmaceutically acceptable salt thereof is provided to the human to affect a shape, contour, or appearance of the human body.

24. A cosmetic method of claim 23 wherein the shape, contour, or appearance is in a region of the body or the eye region of the human.

25. A cosmetic method of claim 23 or the composition for use of claim 15 wherein the reconstituted composition is administered to the human subcutaneously to an abdominal region or an ophthalmic region.

26. A cosmetic method of any of claims 22-25 wherein the composition is administered to the human in the inside region of the knees, the middle to upper area of the upper arm (including the tricep area), the submental area (including the area under the chin, for example the wattle (which is understood to refer to the fleshy fold of skin in the submental area of a patient)), the abdomen, the hips, the inner thigh, the outer thigh, the buttocks, the lower back, the upper back or the chest.

27. A method of preparing a lyophilized sterile salmeterol composition for use as claimed in claims 1 to 21 or in a method of claims 22 to 25 comprising:
(i) solubilizing a salmeterol or a pharmaceutically acceptable salt thereof; and a bulking agent, and optionally a non-ionic surfactant with a solvent or co-solvent to form a bulk solution;
(ii) sterilizing the bulk solution; and
(iii) lyophilizing the sterilized bulk solution to provide a lyophilized sterile salmeterol composition.

28. A method of claim 27 wherein the solvent or co-solvent is selected from tert-butyl alcohol, n-butanol, ethanol, iso-propyl alcohol, dimethyl sulfone, chlorobutanol, or mixtures thereof.

29. A method of claim 28 wherein the solvent or co-solvent is tert-butyl alcohol.

30. A method of claim 27 wherein the sterilizing the bulk solution comprises passing the bulk solution through a filter.

31. A method of claim 30 wherein the filter is a 0.2 micron filter.

32. A method of any of claims 27-30 wherein the pharmaceutically acceptable salt of salmeterol is salmeterol xinafoate.

33. A method of any of claims 27-32 wherein the bulk solution further comprises a non-ionic surfactant is selected from (N,N-Bis[3-(D-gluconamido)propyl]cholamide); Bis(polyethylene glycol bis[imidazoyl carbonyl]); Polyoxyethyleneglycol dodecyl ether; Polyoxyethylenglyceroltriricinoleate 35; decaethylene glycol monododecyl ether; N-decanoyl-N-methylglucamine; n-decyl α-D-glucopyranoside; decyl β-D-maltopyranoside; n-dodecanoyl-N-methylglucamide; n-dodecyl α-D-maltoside; n-dodecyl β-D-maltoside; n-hexadecyl β-D-maltoside; heptaethylene glycol monodecyl ether; heptaethylene glycol monododecyl ether; heptaethylene glycol monotetradecyl ether; hexaethylene glycol monododecyl ether; hexaethylene glycol monohexadecyl ether; hexaethylene glycol monooctadecyl ether; hexaethylene glycol monotetradecyl ether; octylphenyl-polyethylene glycol; methyl-6-O-(N-heptylcarbamoyl)-α-D-glucopyranoside; nonaethylene glycol monododecyl ether; N-nonanoyl-N-methylglucamine; N-nonanoyl-N-methylglucamine; octaethylene glycol monodecyl ether; octaethylene glycol monododecyl ether; octaethylene glycol monohexadecyl ether; octaethylene glycol monooctadecyl ether; octaethylene glycol monotetradecyl ether; octyl- β-D-glucopyranoside; pentaethylene glycol monodecyl ether; pentaethylene glycol monododecyl ether; pentaethylene glycol monohexadecyl ether; pentaethylene glycol monohexyl ether; pentaethylene glycol monooctadecyl ether; pentaethylene glycol monooctyl ether; polyethylene glycol diglycidyl ether; polyethylene glycol ether W-1; polyoxyethylene 10 tridecyl ether; polyoxyethylene 100 stearate; polyoxyethylene 20 isohexadecyl ether; polyoxyethylene 20 oleyl ether; polyoxyethylene 40 stearate; polyoxyethylene 50 stearate; polyoxyethylene 8 stearate, polyoxyethylene bis(imidazolyl carbonyl), polyoxyethylene 25 propylene glycol stearate; saponin; sorbitan laurate, sorbitan monopalmitate, sorbitan stearate, sorbitan tristearate, sorbitan

oleate, sorbitan trioleate; polyethyelene glycol trimethylnonyl ether, nonylphenol ethoxylate; tetradecyl- α-D-maltoside; tetraethylene glycol monodecyl ether, tetraethylene glycol monododecyl ether, tetraethylene glycol monotetradecyl ether; triethylene glycol monodecyl ether, triethylene glycol monododecyl ether, triethylene glycol monohexadecyl ether, triethylene glycol monooctyl ether, triethylene glycol monotetradecyl ether; octoxynol-9; octylphenol ethoxylate; polysorbate 20, polysorbate 21, polysorbate 40, polysorbate 60, polysorbate 61, polysorbate 65, polysorbate 80, polysorbate 81, polysorbate 85; tyloxapol; and n-undecyl β--D-glucopyranoside, and combinations thereof.

34. A reconstitution method of preparing a long-acting salmeterol formulation that is suitable for subcutaneous injection comprising the step of contacting a lyophilized sterile salmeterol composition as claimed in claims 1 to 25 with a pharmaceutically acceptable diluent or carrier.

35. Use of a composition as claimed in claim 1 wherein the salmeterol xinafoate is in a crystalline phase, a polymorph form, an amorphous phase, a semi-crystalline phase, a semi-amorphous phase, or a mixture thereof.

36. Use of claim 35 wherein the polymorph form is a Form I polymorph.

37. Use of claim 35 wherein the polymorph form is a Form II polymorph.

38. Use of any of claims 14-21 comprising salmeterol xinafoate.

39. Use of claim 38 wherein the salmeterol xinafoate is in a crystalline phase, a polymorph form, an amorphous phase, a semi-crystalline phase, a semi-amorphous phase, or a mixture thereof.

40. Use of claim 39 wherein the polymorph form is a Form I polymorph.

41. Use of claim 39 wherein the polymorph form is a Form II polymorph.

42. A method of any of claims 22-34 wherein the pharmaceutically acceptable salt of salmeterol is salmeterol xinafoate.

43. A method of claim 42 wherein the salmeterol xinafoate is in a crystalline phase, a polymorph form, an amorphous phase, a semi-crystalline phase, a semi-amorphous phase, or a mixture thereof.

44. A method of claim 43 wherein the polymorph form is a Form I polymorph.

45. A method of claim 43 wherein the polymorph form is a Form II polymorph.

WHAT IS CLAIMED IS:

1. A lyophile fluticasone composition comprising lyophilized fluticasone or a pharmaceutically acceptable salt thereof, a bulking agent and a non-ionic surfactant.

2. The lyophile fluticasone composition of claim 1 that further comprises a buffering agent.

3. The lyophile fluticasone composition of claim 1 wherein the lyophilized fluticasone is in a crystalline phase, an amorphous phase, a semi-crystalline phase, a semi-amorphous phase, or a mixture thereof.

4. The lyophile fluticasone composition of claim 1 wherein the pharmaceutically acceptable salt is a propionate salt or a furoate salt.

5. The lyophile fluticasone composition of claim 1 wherein the pharmaceutically acceptable salt is the propionate salt.

6. The lyophile fluticasone composition of claim 1 wherein the lyophilized fluticasone is present in an amount of about 0.001 % to about 0.1 % by weight of the total combined dry weight of the lyophile.

7. The lyophile fluticasone composition of claim 1 wherein the lyophilized fluticasone is present in an amount of about 0.015 % to about 0.030 % by weight of the total combined dry weight of the lyophile.

8. The lyophile fluticasone composition of claim 1 wherein the lyophilized fluticasone is present in an amount of about 0.017 % to about 0.023 % by weight of the total combined dry weight of the lyophile.

9. The lyophile fluticasone composition of claim 1 wherein the lyophilized fluticasone is present in an amount equal to or less than about 500 micrograms/gram.

10. The lyophile fluticasone composition of claim 1 wherein the lyophilized fluticasone is present in an amount of about 1 microgram/gram to about 500 micrograms/gram.

11. The lyophile fluticasone composition of claim 1 wherein the lyophilized fluticasone is present in an amount of about 25 micrograms/gram to about 225 micrograms/gram.

12. The lyophile fluticasone composition of claim 1 wherein the lyophilized fluticasone is present in an amount of about 9 micrograms/gram to about 20 micrograms/gram.

13. The lyophile fluticasone composition of claim 1 wherein the non-ionic surfactant is polysorbate 80.

14. The lyophile fluticasone composition of any of claim 1 wherein the bulking agent is selected from the group consisting of lactose, mannitol, dextrose, and sucrose.

15. The lyophile fluticasone composition of claim 1 wherein the non-ionic surfactant is present in an amount of about 1 % to about 10 % by weight of the total combined dry weight of the lyophile and the bulking agent is present in an amount of about 90 % to about 99 % by weight of the total combined dry weight of the lyophile.

16. The lyophile fluticasone composition of claim 1 wherein the composition is stable for a period of at least 6 months at a temperature of about 0 °C to about 50 °C.

17. The lyophile fluticasone composition of claim 1 wherein the composition contains less than about 3 % solvent or co-solvent by weight of the total combined dry weight of the lyophile.

18. The lyophile fluticasone composition of claim 17 wherein the solvent or co-solvent is selected from tert-butyl alcohol, n-butanol, ethanol, iso-propyl alcohol, dimethyl sulfone, chlorobutanol, or mixtures thereof.

19. A sterile fluticasone formulation that has been reconstituted from a lyophilized composition that comprised lyophilized fluticasone or a pharmaceutically acceptable salt thereof, a bulking agent and a non-ionic surfactant.

20. The reconstituted sterile fluticasone formulation of claim 19 further comprising a pharmaceutically acceptable diluent that is selected from Sterile Water for Injection, 0.9% sodium chloride solution, or 5% dextrose solution.

21. The reconstituted sterile fluticasone formulation of claim 19 wherein the pharmaceutically acceptable diluent is Sterile Water for Injection.

22. The reconstituted sterile fluticasone formulation of claim 19 wherein the reconstituted fluticasone is present in an amount that is equal to or less than about 100 micrograms/milliliter.

23. The reconstituted sterile fluticasone formulation of claim 19 wherein the reconstituted fluticasone is present in an amount of about 900 nanograms/milliliter to about 2 micrograms/milliliter.

24. The reconstituted sterile fluticasone formulation of claim 19 wherein the reconstituted fluticasone is present in an amount of about 1 microgram/milliliter.

25. The reconstituted sterile fluticasone formulation of claim 19 wherein the dissolution occurs in less than about 2 minutes.

26. The reconstituted lyophile fluticasone formulation of claim 25 that provides a solubilized or dissolved amount of fluticasone that is at least about 50% of the amount of the lyophilized fluticasone present prior to reconstitution as determined by HPLC after about 2 minutes of dissolution.

27. The reconstituted lyophile fluticasone formulation of claim 25 that provides a solubilized or dissolved amount of fluticasone that is about 90% to about 100% of the amount of lyophilized fluticasone present prior to reconstitution as determined by HPLC after about 2 minutes of dissolution.

28. The reconstituted lyophile fluticasone formulation of claim 27 wherein the non-ionic surfactant was present in the lyophile fluticasone composition prior to reconstitution in an amount of about 4 % to about 5 % of the total combined dry weight of the lyophile.

29. The reconstituted lyophile fluticasone formulation of claim 19 that is formulated to further comprise salmeterol or a pharmaceutically acceptable salt thereof.

30. A cosmetic or therapeutic method or use comprising subcutaneously administering or providing to a human the reconstituted sterile fluticasone formulation of claim 29.

31. The therapeutic method or use of claim 30 wherein the reconstituted sterile fluticasone formulation is administered to the human to treat an indication selected from the group consisting of abdominal adiposity, regional adiposity, and exophthalmos due to thyroid eye disease.

32. A method of preparing a lyophilized sterile fluticasone composition comprising:

(i) solubilizing fluticasone or a pharmaceutically acceptable salt thereof, a bulking agent, and a non-ionic surfactant with a solvent or co-solvent to form a bulk solution;

(ii) sterilizing the bulk solution; and

(iii) lyophilizing the sterilized bulk solution to provide a lyophilized sterile fluticasone composition.

33. A reconstitution method of preparing a fluticasone formulation that is suitable for subcutaneous injection comprising the step of contacting a lyophilized sterile fluticasone composition that further comprises a bulking agent and a non-ionic surfactant with a pharmaceutically acceptable diluent or carrier.

34. A lyophile salmeterol composition comprising lyophilized salmeterol or a pharmaceutically acceptable salt thereof and a bulking agent.

35. The lyophile salmeterol composition of claim 34 that further comprises a buffering agent.

36. The lyophile salmeterol composition of claim 34 that further comprises an anti-oxidant.

37. The lyophile salmeterol composition of claim 34 wherein the lyophilized salmeterol is present in an amount of about 200 nanograms/gram to about 250 nanograms/gram.

38. A sterile salmeterol formulation that has been reconstituted from a lyophilized composition that comprised lyophilized salmeterol or a pharmaceutically acceptable salt thereof and a bulking agent.

39. The reconstituted lyophile salmeterol formulation of claim 38 that is formulated to further comprise fluticasone or a pharmaceutically acceptable salt thereof.

40. The formulation of claim 39 wherein the reconstituted fluticasone is present in an amount of about 100 nanograms/milliliter to about 100 micrograms/milliliter.

41. The formulation of claim 39 wherein the fluticasone is present in an amount of about 900 nanograms/milliliter to about 2 micrograms/milliliter.

42. A cosmetic or therapeutic method or use comprising subcutaneously administering or providing to a human the reconstituted sterile salmeterol formulation of claim 39.

43. A method of preparing a lyophilized sterile salmeterol composition comprising:

(i) solubilizing salmeterol or a pharmaceutically acceptable salt thereof and a bulking agent with a solvent or co-solvent to form a bulk solution;

(ii) sterilizing the bulk solution; and

(iii) lyophilizing the sterilized bulk solution to provide a lyophilized sterile salmeterol composition.

44. A reconstitution method of preparing a salmeterol formulation that is suitable for subcutaneous injection comprising the step of contacting a lyophilized sterile salmeterol composition that further comprises a bulking agent with a pharmaceutically acceptable diluent or carrier.

45. A lyophile composition comprising:

(a) a lyophilized fluticasone or a pharmaceutically acceptable salt thereof;

(b) a lyophilized salmeterol or a pharmaceutically acceptable salt thereof;

(c) a bulking agent; and

(d) a non-ionic surfactant.

46. The lyophile composition of claim 45 wherein the ratio of fluticasone to salmeterol is about 150:1 to about 1:1.

47. The lyophile composition of claim 45 wherein the lyophilized fluticasone is present in an amount that is equal to or less than about 500 micrograms/gram and the lyophilized salmeterol is present in an amount equal to or less than about 250 micrograms/gram.

48. The lyophile composition of claim 45 wherein the lyophilized fluticasone is present in an amount of about 200 micrograms/gram to about 300 micrograms/gram and the lyophilized salmeterol is present in an amount of about 4 micrograms/gram to about 15 micrograms/gram.

49. The lyophile composition of claim 45 wherein the lyophilized fluticasone is present in an amount of about 9 micrograms/gram to about 20 micrograms/gram and the lyophilized salmeterol is present in an amount of about 200 nanograms/gram to about 250 nanograms/gram.

50. A sterile formulation that has been reconstituted from a lyophilized composition that comprised fluticasone or a pharmaceutically acceptable salt thereof; salmeterol or a pharmaceutically acceptable salt thereof; a bulking agent; and a non-ionic surfactant.

51. The reconstituted sterile formulation of claim 47 wherein the reconstituted fluticasone is present in an amount equal to or less than about 100 micrograms/milliliter and the reconstituted salmeterol is present in an amount equal to or less than about 25 micrograms/milliliter.

52. The reconstituted sterile formulation of claim 47 wherein the reconstituted fluticasone is present in an amount of about 900 nanograms/milliliter to about 2 micrograms/milliliter the salmeterol is present in an amount of about 20 nanograms/milliliter to about 25 nanograms/milliliter.

53. A cosmetic or therapeutic method or use comprising subcutaneously administering or providing to a human the reconstituted sterile formulation of claim 50.

54. A method of preparing a lyophilized sterile composition comprising:

(i) solubilizing fluticasone or a pharmaceutically acceptable salt thereof; salmeterol or a pharmaceutically acceptable salt thereof, a bulking agent, and a non-ionic surfactant with a solvent or co-solvent to form a bulk solution;

(ii) sterilizing the bulk solution; and

(iii) lyophilizing the sterilized bulk solution to provide a lyophilized sterile composition.

55. A reconstitution method of preparing a formulation that is suitable for subcutaneous injection comprising the step of contacting with a pharmaceutically acceptable diluent or carrier a lyophilized material comprising:

(a) fluticasone or a pharmaceutically acceptable salt thereof;

(b) salmeterol or a pharmaceutically acceptable salt thereof;

(c) a bulking agent; and

(d) a non-ionic surfactant.