CLAIMS

1. A reusable vaginal system for preventing pregnancy comprising: a silicone elastomer ring body having a platinum concentration of approximately 3 ppm to approximately 10 ppm and a hydride/vinyl ratio from approximately 1:1 to approximately 1.3:1 before curing, wherein the silicone elastomer ring body comprises two cores, each core comprising a condensation-cure silicone elastomer and dibutyltin dilaurate; the cores containing, in total, approximately 103 mg of segesterone acetate, and approximately 17.4 mg of ethinyl estradiol;

wherein the system is configured to release an approximate average of 0.15 mg/day of segesterone acetate and an approximate average of 0.013 mg/day of ethinyl estradiol, or bioequivalent amounts thereof, for up to 13 cycles of 21 days each; and

wherein approximately 80% to approximately 90% of the ethinyl estradiol is recoverable from the system after approximately 18 months of storage at 25°C and 60% relative humidity and wherein no more than approximately 10% to approximately 20% of the ethinyl estradiol undergoes hydrosilylation with unreacted hydrosilane in the ring body after approximately 18 months of storage at 25°C and 60% relative humidity.

2. The vaginal system of claim 1, wherein one of the two cores contains segesterone acetate and the other contains segesterone acetate and ethinyl estradiol, and wherein the core that contains segesterone acetate and ethinyl estradiol is cured at a temperature from approximately 60°C to approximately 90°C.

3. The vaginal system of claim 2, wherein the core that contains segesterone acetate and ethinyl estradiol is cured at a relative humidity of approximately 1% to approximately 2%.

4. The vaginal system of claim 1, wherein one of the two cores contains segesterone acetate and the other contains segesterone acetate and ethinyl estradiol, and wherein the core that contains segesterone acetate and ethinyl estradiol is aged for at least 30 days before being assembled into the ring body.

5. A multi-component 13-cycle vaginal system for preventing pregnancy, the system comprising:

a. a silicone elastomer ring body adapted to receive first and second drug-containing cores, the ring body comprising a silicone elastomer which has a platinum concentration of approximately 3 ppm to approximately 10 ppm and a hydride/vinyl ratio from approximately 1:1 to approximately 1.3:1 before curing;

b. first and second cores comprising, in total, approximately 103 mg of segesterone acetate and approximately 17.4 mg of ethinyl estradiol, each core further comprising one or more condensation-cure silicone elastomers and dibutyltin dilaurate; wherein the system is configured to release an approximate average of 0.15 mg/day of segesterone acetate and an approximate average of 0.013 mg/day of ethinyl estradiol, or a bioequivalent amount of either or both, for up to 13 cycles of 21 days each; and wherein approximately 80% to approximately 90% of the ethinyl estradiol is recoverable from the system after approximately 18 months of storage at 25°C and 60% relative humidity.

6. A multi-component vaginal system for preventing pregnancy, the system comprising:

a. a silicone elastomer ring body adapted to receive first and second drug-containing cores, the ring body comprising a silicone elastomer having a hydride/vinyl ratio from approximately 1:1 to approximately 1.3:1 before curing and a platinum concentration of approximately 3 ppm to approximately 10 ppm;

b. first and second cores comprising, in total, approximately 103 mg of segesterone acetate and approximately 17.4 mg of ethinyl estradiol, each core comprising one or more condensation-cure silicone elastomers and dibutyltin dilaurate;

wherein the system is configured to release an approximate average of 0.15 mg/day of segesterone acetate and an approximate average of 0.013 mg/day of ethinyl estradiol, or a bioequivalent amount of either or both, for up to 13 cycles of 21 days; and

wherein no more than approximately 10% to approximately 20% of the ethinyl estradiol undergoes hydrosilylation with unreacted hydrosilane in the ring body after approximately 18 months of storage at 25°C and 60% relative humidity.

7. A reusable 13-cycle vaginal system for preventing pregnancy comprising: a silicone elastomer ring body having a platinum concentration of approximately 3 ppm to approximately 10 ppm and a hydride/vinyl ratio from approximately 1:1 to approximately

1.3:1 before curing, wherein the silicone elastomer ring body comprises two drug-containing cores, each core comprising segesterone acetate, ethinyl estradiol, or a combination thereof, and each core further comprising one or more condensation-cure silicone elastomers and dibutyltin dilaurate;

the silicone elastomer ring body having a shore A hardness of approximately 25 to approximately 30, a mean fatigue parallel to the cores of approximately 95% and a mean fatigue perpendicular to the cores of approximately 98%;

wherein the system is configured to release an approximate average of 0.15 mg/day of segesterone acetate and an approximate average of 0.013 mg/day of ethinyl estradiol, or a bioequivalent amount of either or both, for up to 13 cycles of 21 days each; and

wherein approximately 80% to approximately 90% of the ethinyl estradiol is recoverable from the system after approximately 18 months of storage at 25°C and 60% relative humidity.

8. A multi-component 13-cycle vaginal system for preventing pregnancy, the system comprising:

a. a silicone elastomer ring body comprising a silicone elastomer which has a hydride/vinyl ratio from approximately 1:1 to approximately 1.3:1 before curing and a platinum concentration of approximately 3 ppm to approximately 10 ppm;

b. a first core comprising first and second condensation-cure silicone elastomers, dibutyltin dilaurate, and a viscosity agent, the first and second silicone elastomers impregnated with a first amount of segesterone acetate particles having a particle size distribution: D90 of not more than 10 microns and a D50 of not more than 5 microns;

c. a second core comprising a third condensation-cure silicone elastomer and dibutyltin dilaurate, wherein the third silicone elastomer is impregnated with a second amount of segesterone acetate particles and an amount of ethinyl estradiol particles, further wherein the ethinyl estradiol particles have a particle size distribution of 100% max 15 microns, 99% max 12.5 microns, 95% max 10 microns and max 40% less than or equal to 1.3 microns;

wherein the first, second, and third silicone elastomers contain in total, approximately 103 mg of segesterone acetate and approximately 17.4 mg of ethinyl estradiol;

wherein the ring system is configured to release an average of 0.15 mg/day of segesterone acetate and an average of 0.013 mg/day of ethinyl estradiol, or a bioequivalent amount of either or both, for up to 13 cycles of 21 days each; and

wherein no more than approximately 10% to approximately 20% of the ethinyl estradiol undergoes hydrosilylation with the unreacted hydrosilane in the ring body after approximately 18 months of storage at 25°C and 60% relative humidity.

9. The vaginal system of claim 8, wherein at least 75% of the segesterone acetate comprises segesterone acetate Polymorphic form I.

10. The vaginal system of claim 8, wherein the segesterone acetate comprises up to 25% segesterone acetate Polymorphic form II.

11. The vaginal system of claim 8, wherein the second core is cured at a temperature from approximately 60°C to approximately 90°C.

12. The vaginal system of claim 11, wherein the second core is cured at a relative humidity of approximately 1% to 2%.

13. A 13-cycle vaginal system for preventing pregnancy, the ring system comprising:

a. a silicone elastomer ring body having a hydride/vinyl ratio from approximately 1:1 to approximately 1.3:1 before curing and a platinum concentration of approximately 3 ppm to approximately 10 ppm;

b. segesterone acetate particles having a particle size distribution: D90 of not more than 10 microns; D50 of not more than 5 microns; and a D10 of not less than 0.6 microns;

c. ethinyl estradiol particles having a particle size distribution of 100% max 15 microns, 99% max 12.5 microns, 95% max 10 microns and max 40% less than or equal to 1.3 microns; wherein the system contains, in total, approximately 103 mg of segesterone acetate and approximately 17.4 mg of ethinyl estradiol.