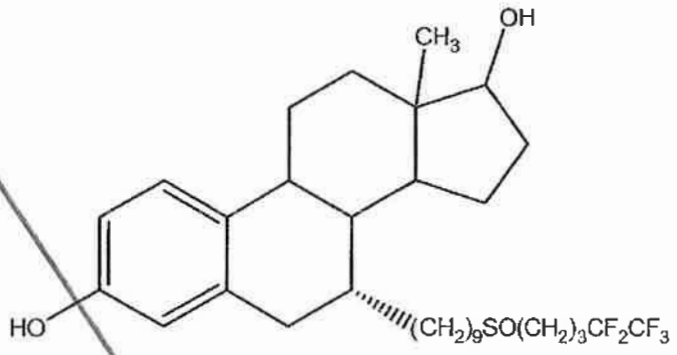
What is claimed is:

1. An inclusion complex comprising a) a cyclodextrin; and b) a compound of the formula (I):



(I)

or a salt thereof or hydrate of the foregoing; and c) a carrier.

2. The inclusion complex of claim 1, wherein the molar ratio of the compound of formula (I) to the cyclodextrin is from about 1:1 to about 1:300.
3. The inclusion complex of claim 1, wherein the inclusion complex increases the solubility of the compound of formula (I), in deionized water at 20 °C, by at least about or about 1.5-fold compared to the solubility of the compound of formula (I) in uncomplexed form under the same conditions.
4. The inclusion complex of claim 1, wherein the inclusion complex increases the oral bioavailability of the compound of formula (I) by at least about or about 50% over the oral bioavailability of the compound of formula (I) in uncomplexed form.
5. The inclusion complex of claim 1, wherein the inclusion complex is capable of inducing at least about or about 2-times greater C_{max} of the compound of formula (I) than what is achievable when the compound is administered alone in the same amount and under the same conditions.
6. The inclusion complex of any one of claims 1-5, wherein the cyclodextrin is a

water soluble unsubstituted or substituted alpha-cyclodextrin, beta-cyclodextrin, or gamma- cyclodextrin.

7. The inclusion complex of claim 6, wherein the beta-cyclodextrin is selected from the group consisting of methyl beta-cyclodextrin, hydroxypropyl beta-cyclodextrin, and sulfobutylether beta-cyclodextrin.

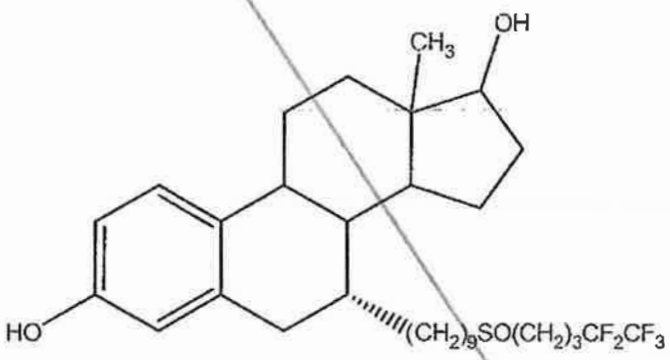
8. The inclusion complex of claim 7, wherein the beta-cyclodextrin is methyl beta-cyclodextrin.

9. The inclusion complex of claim 7, wherein the beta-cyclodextrin is hydroxypropyl beta-cyclodextrin.

10. The inclusion complex of claim 6, wherein the gamma-cyclodextrin is hydroxypropyl gamma-cyclodextrin.

11. The inclusion complex of any one of claims 1-10, wherein the compound of formula (I) is fulvestrant sulphoxide A, fulvestrant sulphoxide B, or a mixture of fulvestrant sulphoxide A and fulvestrant sulphoxide B.

12. A formulation comprising a) a cyclodextrin; b) a compound of the formula (I):



(I)

or a salt thereof or hydrate of the foregoing; and c) a carrier.

13. The formulation of claim 12, wherein the carrier is a pharmaceutically acceptable carrier.

14. A formulation comprising an effective amount of the inclusion complex of any of claims 1-11 and a carrier, wherein the carrier is selected from the group

consisting of a solvent, a mixed solvent, a complexing agent, a filler, a diluent, a granulating agent, a disintegrant, a lubricant, a glidant, a pH-modifier, a tonicity modifier, an adjuvant, and a binder.

15. The formulation of claim 12, wherein the carrier is one or more of water for injection, microcrystalline cellulose, glucose, sodium lauryl sulphate, crosscarmellose sodium, colloidal silica, talc, magnesium stearate, sodium benzoate, aluminum magnesium silicate, lactose, a dye, a polymer-based film coating, methanol, ethanol, propanol, and acetone.

16. The formulation of claim 12, wherein the formulation is a solid.

17. The formulation of claim 12, wherein the formulation is a liquid.

18. The formulation of claim 12, wherein the compound of the formula (I) is present in an amount between about 0.1 mg and about 500 mg per unit dose of the compound of the formula (I).

19. The formulation of claim 12, wherein the formulation further comprises an antioxidant.

20. The formulation of claim 19, wherein the antioxidant is selected from the group consisting of ascorbyl palmitate, butylated hydroxyanisole, butylated hydroxytoluene, malic acid, propyl gallate, sodium bisulfite, sodium sulfite, sodium metabisulfite, potassium metabisulfite, potassium bisulfite, sodium thiosulfate, sodium formaldehyde sulfoxylate, L-ascorbic acid, D-ascorbic acid, acetylcysteine, cysteine, thioglycerol, thioglycolic acid, thiolactic acid, thiourea, dithiothreitol, dithioerythreitol, glutathione, nordihydroguaiaretic acid, tocopherol, sodium ascorbate, hypophophorous acid, and fumaric acid.

21. The formulation of claim 19, wherein the antioxidant is a dietary antioxidant.

22. A substantially pure form of the inclusion complex of any one of claims 1-11.

23. A method of treating a disease or condition that is or is believed to be responsive to anti-estrogen therapy and/or ER-downregulation in an individual in need thereof, comprising administering to the individual an effective amount of the inclusion complex of any one of claims 1-11 or a formulation of any one of claims 12-21.

24. The method of claim 23, wherein the disease or condition is cancer.

25. The method of claim 24, wherein the cancer is early stage cancer, non-metastatic cancer, primary cancer, advanced cancer, locally advanced cancer, metastatic cancer, cancer in remission, recurrent cancer, cancer in an adjuvant setting, cancer in a neoadjuvant setting, or cancer substantially refractory to hormone therapy.
26. The method of claim 24, wherein the cancer is selected from the group consisting of breast cancer, endometrial cancer, prostate cancer, and lung cancer.
27. The method of claim 24, wherein the cancer is hormone receptor positive metastatic breast cancer.
28. The method of claim 23, wherein the inclusion complex is intranasally, orally, sublingually, rectally, or vaginally administered to the individual.
29. The method of claim 23, wherein the disease or condition is systemic lupus erythematosus.
30. The method of any of claims 23-29, wherein the method further comprises administering one other pharmaceutical agent.
31. The method of claim 30, wherein the other agent is an anti-cancer agent.
32. The method of claim 30, wherein the inclusion complex and the other agent are administered simultaneously or sequentially.
33. The method of claim 30, wherein the inclusion complex and the other agent are administered concurrently.
34. The method of claim 30, wherein the other agent is selected from the group consisting of anastrozole, letrozole, exemestane, aminoglutethimide, vorozole, formestane, fadrozole, testolactone, gefitinib, trastuzumab, erlotinib, tipifarnib, uncomplexed fulvestrant, and an antioxidant.
35. The method of claim 30, wherein the other agent is an uncomplexed fulvestrant or FASLODEX®.
36. A kit comprising the inclusion complex of any one of claims 1-11 or a formulation of any one of claims 12-21.
37. The kit of claim 36, wherein the kit further comprises instructions for use.
38. The kit of claim 37, wherein the kit comprises instructions for use in the treatment of a disease or condition that is or is believed to be responsive to anti-

estrogen therapy and/or ER-downregulation.

39. The kit of claim 38, wherein the kit comprises instructions for use in the treatment of cancer.

40. The kit of any of claims 36-39, wherein the kit further comprises at least one other pharmaceutical agent.

41. The kit of claim 40, wherein the one other pharmaceutical agent is an anti-cancer agent.

42. The kit of claim 40, wherein the other agent is selected from the group consisting of anastrozole, letrozole, exemestane, aminoglutethimide, vorozole, formestane, fadrozole, testolactone, gefitinib, trastuzumab, erlotinib, tipifarnib, uncomplexed fulvestrant, and an antioxidant.

43. A method of producing the inclusion complex of claim 1, comprising admixing the compound of the formula (I) with the cyclodextrin.

44. The method of claim 43, further comprising adding a solvent, mixed solvent, or buffer to the compound of the formula (I), the cyclodextrin, and/or mixture thereof.

45. A method of producing the inclusion complex of claim 1, comprising the steps of:

a. admixing the compound of the formula (I) and the cyclodextrin; and

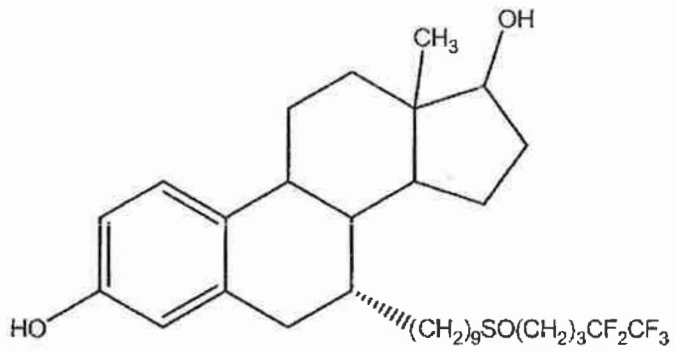
b. adding a suitable amount of solvent, mixed solvent, or buffer to the mixture of step (a) and mixing until a suspension or solution is formed.

46. The method of claim 45, wherein the buffer is a phosphate-citrate buffer.

47. The method of claim 45, wherein step (a) further comprises admixing a suitable polymer.

48. The method of claim 47, wherein the suitable polymer is selected from the group consisting of polyvinylpyrrolidone, hydroxypropyl methylcellulose, carboxymethylcellulose, and PLASDONE® Povidone.

49. A method for improving solubility of a compound of the formula (I):



(I)

or a salt, hydrate, or solvate thereof in water comprising complexing the compound of the formula (I) with a cyclodextrin.

50. A unit dosage form comprising the inclusion complex of any of claims 1-11.

51. The use of an inclusion complex as defined in any one of claims 1-11 in a method of manufacturing a medicament for use in a method of treating a disease or condition that is or is believed to be responsive to anti-estrogen therapy and/or ER-downregulation in an individual in need thereof.

52. The use of claim 51, wherein the disease or condition is cancer.

53. The use of claim 52, wherein the cancer is early stage cancer, non-metastatic cancer, primary cancer, advanced cancer, locally advanced cancer, metastatic cancer, cancer in remission, recurrent cancer, cancer in an adjuvant setting, cancer in a neoadjuvant setting, or cancer substantially refractory to hormone therapy.

54. The use of claim 52, wherein the cancer is selected from the group consisting of breast cancer, endometrial cancer, prostate cancer, and lung cancer.

55. The use of claim 52, wherein the cancer is hormone receptor positive metastatic breast cancer.

56. The use of claim 51, wherein the inclusion complex is intranasally, orally, sublingually, rectally, or vaginally administered to the individual.

57. The use of claim 51, wherein the disease or condition is systemic lupus erythematosus.

58. The use of any of claims 51-57, wherein the method of treatment further comprises administering one other pharmaceutical agent.

59. The use of claim 58, wherein the other agent is an anti-cancer agent.

60. The use of claim 58, wherein the inclusion complex and the other agent are administered simultaneously or sequentially.

61. The use of claim 58, wherein the inclusion complex and the other agent are administered concurrently.

62. The use of claim 58, wherein the other agent is selected from the group consisting of anastrozole, letrozole, exemestane, aminoglutethimide, vorozole, formestane, fadrozole, testolactone, gefitinib, trastuzumab, erlotinib, tipifarnib, uncomplexed fulvestrant, and an antioxidant.

63. The use of claim 58, wherein the other agent is an uncomplexed fulvestrant or FASLODEX®.

64. An inclusion complex as defined in any one of claims 1-11, for use in the treatment of a disease or condition that is or is believed to be responsive to anti-estrogen therapy and/or ER-downregulation in an individual in need thereof.

65. The inclusion complex of claim 64, wherein the disease or condition is cancer.

66. The inclusion complex of claim 65, wherein the cancer is early stage cancer, non-metastatic cancer, primary cancer, advanced cancer, locally advanced cancer, metastatic cancer, cancer in remission, recurrent cancer, cancer in an adjuvant setting, cancer in a neoadjuvant setting, or cancer substantially refractory to hormone therapy.

67. The inclusion complex of claim 65, wherein the cancer is selected from the group consisting of breast cancer, endometrial cancer, prostate cancer, and lung cancer.

68. The inclusion complex of claim 65, wherein the cancer is hormone receptor positive metastatic breast cancer.

69. The inclusion complex of claim 64, wherein the inclusion complex is intranasally, orally, sublingually, rectally, or vaginally administered to the individual.

70. The inclusion complex of claim 64, wherein the disease or condition is systemic lupus erythematosus.

71. The inclusion complex of any of claims 64-70, wherein the treatment further comprises administering one other pharmaceutical agent.

72. The inclusion complex of claim 71, wherein the other agent is an anti-cancer agent.

73. The inclusion complex of claim 71, wherein the inclusion complex and the other agent are administered simultaneously or sequentially.

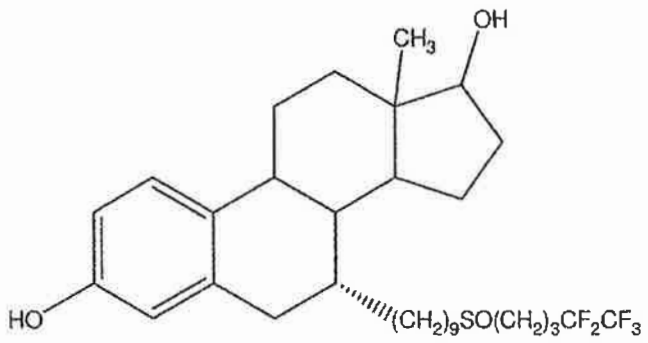
74. The inclusion complex of claim 71, wherein the inclusion complex and the other agent are administered concurrently.

75. The inclusion complex of claim 71, wherein the other agent is selected from the group consisting of anastrozole, letrozole, exemestane, aminoglutethimide, vorozole, formestane, fadrozole, testolactone, gefitinib, trastuzumab, erlotinib, tipifarnib, uncomplexed fulvestrant, and an antioxidant.

76. The inclusion complex of claim 71, wherein the other agent is an uncomplexed fulvestrant or FASLODEX®.

WHAT WE CLAIM IS:

1. An inclusion complex comprising a) a cyclodextrin; and b) a compound of the formula (I):



(I)

or a salt thereof or hydrate of the foregoing; and c) a carrier.

2. The inclusion complex of claim 1, wherein the molar ratio of the compound of formula (I) to the cyclodextrin is from about 1:1 to about 1:300.

3. The inclusion complex of claim 1, wherein the inclusion complex increases the solubility of the compound of formula (I), in deionized water at 20 °C, by at least about or about 1.5-fold compared to the solubility of the compound of formula (I) in uncomplexed form under the same conditions.

4. The inclusion complex of claim 1, wherein the inclusion complex increases the oral bioavailability of the compound of formula (I) by at least about or about 50% over the oral bioavailability of the compound of formula (I) in uncomplexed form.

5. The inclusion complex of claim 1, wherein the inclusion complex is capable of inducing at least about or about 2-times greater C_{max} of the compound of formula (I) than what is achievable when the compound is administered alone in the same amount and under the same conditions.

6. The inclusion complex of any one of claims 1-5, wherein the cyclodextrin is a water soluble unsubstituted or substituted alpha-cyclodextrin, beta-cyclodextrin, or gamma-cyclodextrin.

7. The inclusion complex of claim 6, wherein the beta-cyclodextrin is selected from the group consisting of methyl beta-cyclodextrin, hydroxypropyl beta cyclodextrin, and sulfobutylether beta-cyclodextrin.

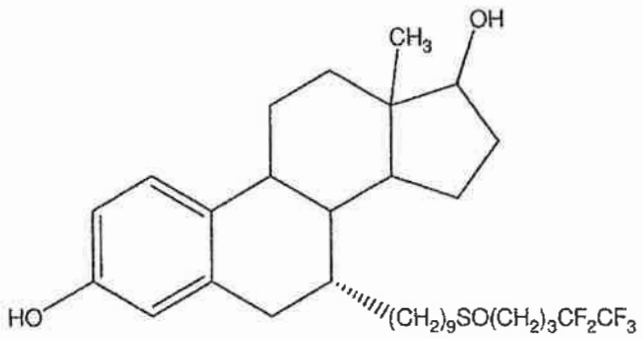
8. The inclusion complex of claim 7, wherein the beta-cyclodextrin is methyl beta-cyclodextrin.

9. The inclusion complex of claim 7, wherein the beta-cyclodextrin is hydroxypropyl beta-cyclodextrin.

10. The inclusion complex of claim 6, wherein the gamma-cyclodextrin is hydroxypropyl gamma-cyclodextrin.

11. The inclusion complex of any one of claims 1-10, wherein the compound of formula (I) is fulvestrant sulphoxide A, fulvestrant sulphoxide B, or a mixture of fulvestrant sulphoxide A and fulvestrant sulphoxide B.

12. A formulation comprising a) a cyclodextrin; b) a compound of the formula (I):



(I)

or a salt thereof or hydrate of the foregoing; and c) a carrier.

13. The formulation of claim 12, wherein the carrier is a pharmaceutically acceptable carrier.

14. A formulation comprising an effective amount of the inclusion complex of any of claims 1-11 and a carrier, wherein the carrier is selected from the group consisting of a solvent, a mixed solvent, a complexing agent, a filler, a diluent, a granulating agent, a disintegrant, a lubricant, a glidant, a pH-modifier, a tonicity modifier, an adjuvant, and a binder.

15. The formulation of claim 12, wherein the carrier is one or more of water for injection, microcrystalline cellulose, glucose, sodium lauryl sulphate, crosscarmellose sodium, colloidal silica, talc, magnesium stearate, sodium benzoate, aluminum magnesium silicate, lactose, a dye, a polymer-based film coating, methanol, ethanol, propanol, and acetone.

16. The formulation of claim 12, wherein the formulation is a solid.

17. The formulation of claim 12, wherein the formulation is a liquid.

18. The formulation of claim 12, wherein the compound of the formula (I) is present in an amount between about 0.1 mg and about 500 mg per unit dose of the compound of the formula (I).

19. The formulation of claim 12, wherein the formulation further comprises an antioxidant.

20. The formulation of claim 19, wherein the antioxidant is selected from the group consisting of ascorbyl palmitate, butylated hydroxyanisole, butylated hydroxytoluene, malic acid, propyl gallate, sodium bisulfite, sodium sulfite, sodium metabisulfite, potassium metabisulfite, potassium bisulfite, sodium thiosulfate, sodium formaldehyde sulfoxylate, L-ascorbic acid, D-ascorbic acid, acetylcysteine, cysteine, thioglycerol, thioglycoUic acid, thiolactic acid, thiourea, dithiothreitol, dithioerythreitol, glutathione, nordihydroguaiaretic acid, tocopherol, sodium ascorbate, hypophophorous acid, and fumaric acid.

21. The formulation of claim 19, wherein the antioxidant is a dietary antioxidant.

22. A substantially pure form of the inclusion complex of any one of claims 1-11.

23. A kit comprising the inclusion complex of any one of claims 1-11 or a formulation of any one of claims 12-21.

24. The kit of claim 23, wherein the kit further comprises instructions for use.

25. The kit of claim 24, wherein the kit comprises instructions for use in the treatment of a disease or condition that is or is believed to be responsive to anti-estrogen therapy and/or ER-downregulation.

26. The kit of claim 25, wherein the kit comprises instructions for use in the treatment of cancer.

27. The kit of any one of claims 23-26, wherein the kit further comprises at least one other pharmaceutical agent.

28. The kit of claim 27, wherein the one other pharmaceutical agent is an anti-cancer agent.

29. The kit of claim 27, wherein the other agent is selected from the group consisting of anastrozole, letrozole, exemestane, aminoglutethimide, vorozole, formestane, fadrozole, testolactone, gefitinib, trastuzumab, erlotinib, tipifarnib, uncomplexed fulvestrant, and an antioxidant.

30. A method of producing the inclusion complex of claim 1, comprising admixing the compound of the formula (I) with the cyclodextrin.

31. The method of claim 30, further comprising adding a solvent, mixed solvent, or buffer to the compound of the formula (I), the cyclodextrin, and/or mixture thereof.

32. A method of producing the inclusion complex of claim 1, comprising the steps of:

a. admixing the compound of the formula (I) and the cyclodextrin; and

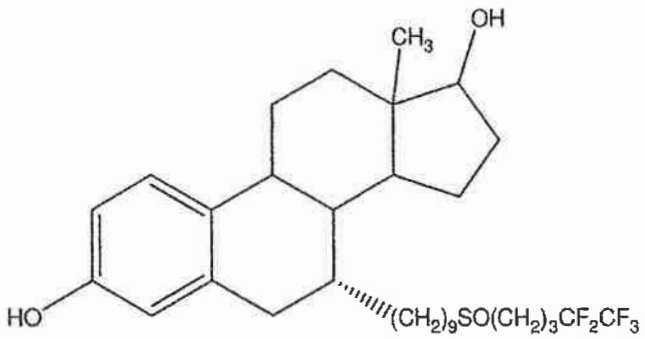
b. adding a suitable amount of solvent, mixed solvent, or buffer to the mixture of step (a) and mixing until a suspension or solution is formed.

33. The method of claim 32, wherein the buffer is a phosphate-citrate buffer.

34. The method of claim 32, wherein step (a) further comprises admixing a suitable polymer.

35. The method of claim 34, wherein the suitable polymer is selected from the group consisting of polyvinylpyrrolidone, hydroxypropyl methylcellulose, carboxymethylcellulose, and N-vinyl-2-pyrrolidone.

36. A method for improving solubility of a compound of the formula (I):



(I)

or a salt, hydrate, or solvate thereof in water comprising complexing the compound of the formula (I) with a cyclodextrin.

37. An inclusion complex prepared by the method of any one of claims 30-35.

38. A unit dosage form comprising the inclusion complex of any of claims 1-11 or 37.

39. The use of an inclusion complex as defined in any one of claims 1-11 or 37 in a method of manufacturing a medicament for use in a method of treating a cancer that is responsive to anti-estrogen therapy and/or ER-downregulation in an individual in need thereof.

40. The use of claim 39, wherein the cancer is early stage cancer, non-metastatic cancer, primary cancer, advanced cancer, locally advanced cancer, metastatic cancer, cancer in remission, recurrent cancer, cancer in an adjuvant setting, cancer in a neoadjuvant setting, or cancer substantially refractory to hormone therapy.

41. The use of claim 39, wherein the cancer is selected from the group consisting of breast cancer, endometrial cancer, prostate cancer, and lung cancer.

42. The use of claim 39, wherein the cancer is hormone receptor positive metastatic breast cancer.

43. The use of claim 39, wherein the inclusion complex is to be intranasally, orally, sublingually, rectally, or vaginally administered to the individual.

44. The use of claim 39, wherein the disease or condition is systemic lupus erythematosus.

45. The use of any of claims 39-43, wherein the method of treatment further comprises administering one other pharmaceutical agent.

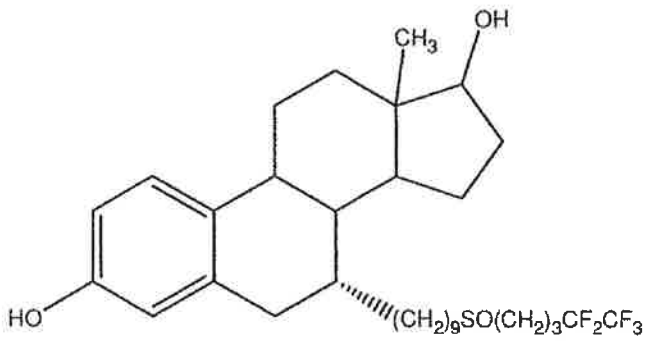
46. The use of claim 45, wherein the other agent is an anti-cancer agent.

47. The use of claim 45, wherein the inclusion complex and the other agent are to be administered simultaneously or sequentially.

48. The use of claim 45, wherein the inclusion complex and the other agent are to be administered concurrently.

49. The use of claim 45, wherein the other agent is selected from the group consisting of anastrozole, letrozole, exemestane, aminoglutethimide, vorozole, formestane, fadrozole, testolactone, gefitinib, trastuzumab, erlotinib, tipifarnib, uncomplexed fulvestrant, and an antioxidant.

50. The use of claim 45, wherein the other agent is an uncomplexed fulvestrant or Fulvestrant (7-alpha-[9-(4,4,5,5,5-penta fluoropentylsulphinyl)nonyl]estra-l,3,5-(10)-triene-3,17-beta-diol), has the structural formula (I):



(I)

51. An inclusion complex as claimed in claim 1 and 37, substantially as herein described with reference to any example thereof.

52. A formulation as claimed in claim 12 or 14, substantially as herein described with reference to any example thereof.

53. A substantially pure form of the inclusion complex as claimed in claim 22, substantially as herein described with reference to any example thereof.

54. A kit as claimed in claim 23, substantially as herein described with reference to any example thereof.

55. A method as claimed in any one of claims 30, 32 and 36, substantially as herein described with reference to any example thereof.

56. A unit doage form as claimed in claim 38, substantially as herein described with reference to any example thereof.

57. A use as claimed in claim 39, substantially as herein described with reference to any example thereof.