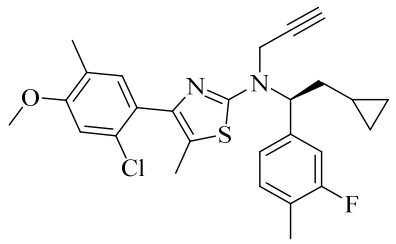
WHAT IS CLAIMED IS:

1. Use of a compound of Formula (I):



(I),

or a pharmaceutically acceptable salt thereof;

in the manufacture of a medicament for treating congenital adrenal hyperplasia in a subject,

wherein the compound of Formula (I), or a pharmaceutically acceptable salt thereof, is to be administered at a frequency of not less than twice daily; and

wherein the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, in the first administration is less than the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, in the second and any subsequent administrations.

2. The use of claim 1, wherein the compound of Formula (I), or a pharmaceutically acceptable salt thereof, is to be administered at a frequency of twice daily.

3. The use of claim 2, wherein the ratio of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, in the first administration to the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, in the second administration is from 1:1.1 to 1:100.

4. The use of claim 2, wherein the ratio of the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, in the first administration to the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, in the second administration is about 1:2.

5. The use of any one of claims 1 to 4, wherein the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, to be administered daily is from about 50 mg to about 1000 mg based on the weight of the free base.

6. The use of any one of claims 1 to 4, wherein the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, to be administered daily is about 300 mg based on the weight of the free base.

7. The use of claim 6, wherein the first administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof is about 100 mg based on the weight of the free base and the second administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof is about 200 mg based on the weight of the free base.

8. The use of any one of claims 1 to 7, wherein the subject weighs greater than or equal to about 55 kg.

9. The use of any one of claims 1 to 4, wherein the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, to be administered daily is about 50 mg based on the weight of the free base.

10. The use of claim 9, wherein the subject weighs from about 10 kg to about 20 kg.

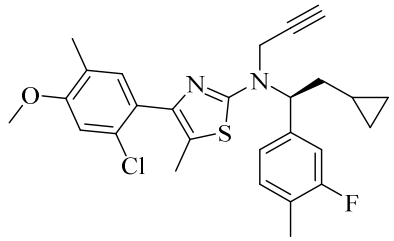
11. The use of any one of claims 1 to 4, wherein the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, to be administered daily is about 100 mg based on the weight of the free base.

12. The use of claim 11, wherein the wherein the first administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof is about 25

mg based on the weight of the free base and the second administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof is about 75 mg based on the weight of the free base.

13. The use of claim 11 or 12, wherein the subject weighs from about 20 kg to about 55 kg.

14. Use of a compound of Formula (I):



(I),

or a pharmaceutically acceptable salt thereof;

in the manufacture of a medicament for treating congenital adrenal hyperplasia in a subject,

wherein the compound of Formula (I), or a pharmaceutically acceptable salt thereof, is to be administered at a frequency of not less than twice daily; and

wherein the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, to be administered daily is greater than 200 mg based on the weight of the free base.

15. The use of claim 14, whererin the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, is to be administered at a frequency of twice daily.

16. The use of claim 14 or 15, wherein the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, to be administered daily is from about 200 mg to about 1000 mg based on the weight of the free base.

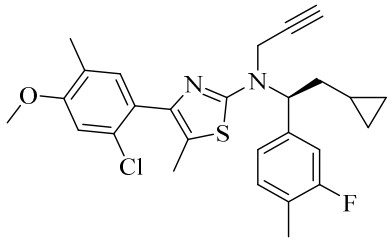
17. The use of any one of claims 1 to 16, wherein the compound of Formula (I), or a pharmaceutically acceptable salt thereof, is to be administered in an amount sufficient to reduce the level of one or more biomarkers selected from (a) 17-hydroxyprogesterone (17-OHP); (b) adrenocorticotropic hormone (ACTH); and (c) androstenedione in the subject.

18. The use of claim 17, wherein the level of 17-hydroxyprogesterone is reduced by at least 25%.

19. The use of claim 17 or 18, wherein the level of adrenocorticotropic hormone is reduced by at least 25%.

20. The use of any one of claims 17 to 19, wherein the level of androstenedione is reduced by at least 25%.

21. Use of a compound of Formula (I):



(I)

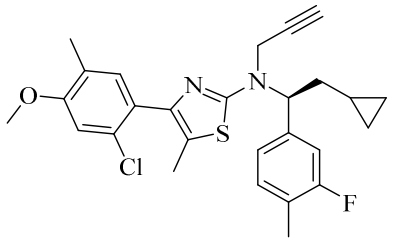
or a pharmaceutically acceptable salt thereof;

in the manufacture of a medicament for reducing the severity of one or more symptoms selected from hirsutism, precocious puberty, fertility problems, acne, and growth impairment in a subject having classic congenital adrenal hyperplasia,

wherein the compound of Formula (I), or a pharmaceutically acceptable salt thereof, is to be administered at a frequency of not less than twice daily; and

wherein the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, in the first administration is less than the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, in the second and any subsequent administrations.

22. Use of a compound of Formula (I):



(I),

or a pharmaceutically acceptable salt thereof,

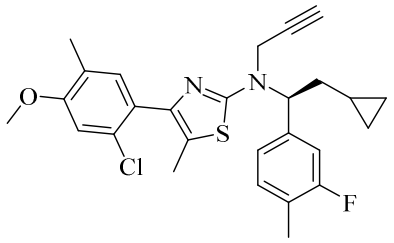
in the manufacture of a medicament for reducing the level of one or more biomarkers of congenital adrenal hyperplasia in a subject having congenital adrenal hyperplasia,

wherein the compound of Formula (I), or a pharmaceutically acceptable salt thereof, is to be administered at a frequency of not less than twice daily; and

wherein the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, in the first administration is less than the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, in the second and any subsequent administrations.

23. The compound of claim 22, wherein the one or more biomarkers of congenital adrenal hyperplasia are selected from (a) 17-hydroxyprogesterone (17-OHP); (b) adrenocorticotropic hormone (ACTH); and (c) androstenedione.

24. Use of a compound of Formula (I):



(I),

or a pharmaceutically acceptable salt thereof;

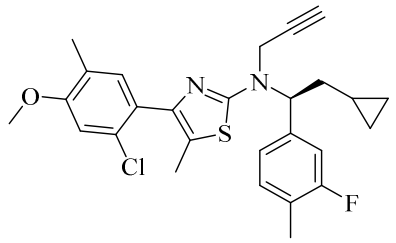
in the manufacture of a medicament for reducing the dosage of corticosteroid administered to a subject having congenital adrenal hyperplasia for controlling congenital adrenal hyperplasia,

wherein the compound of Formula (I), or a pharmaceutically acceptable salt thereof, is to be administered at a frequency of not less than twice daily; and

wherein the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, in the first administration is less than the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, in the second and any subsequent administrations.

25. The use of claim 24, wherein the corticosteroid is a glucocorticoid.

26. Use of a compound of Formula (I):



(I),

or a pharmaceutically acceptable salt thereof,

in the manufacture of a medicament for reducing the severity of one or more side effects of glucocorticoid treatment in a subject having congenital adrenal hyperplasia,

wherein the compound of Formula (I), or a pharmaceutically acceptable salt thereof, is to be administered at a frequency of not less than twice daily;

wherein the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, in the first administration is less than the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, in the second and any subsequent administrations; and

wherein the side effect is selected from osteoporosis, avascular necrosis of bone, myopathy, hyperglycemia, diabetes mellitus, dyslipidemia, weight gain, Cushing syndrome, Cushingoid features, growth suppression, adrenal suppression,

gastritis, peptic ulcer, gastrointestinal bleeding, visceral perforation, hepatic steatosis, pancreatitis, hypertension, coronary heart disease, ischemic heart disease, heart failure, dermatoprosis, skin atrophy, ecchymosis, purpura, erosions, striae, delayed wound healing, easy bruising, acne, hirsutism, hair loss, mood changes, depression, euphoria, mood lability, irritability, akathisia, anxiety, cognitive impairment, psychosis, dementia, delirium, cataract, glaucoma, ptosis, mydriasis, opportunistic ocular infections, central serous chorioretinopathy, suppression of cell-mediated immunity, predisposition to infections, and reactivation of latent infections.

27. The use of any one of claims 21 to 26, wherein the compound of Formula (I), or a pharmaceutically acceptable salt thereof, is to be administered twice daily as:

(a) a first administration of about 50 mg based on the weight of the free base and a second administration of about 150 mg based on the weight of the free base; or

(b) a first administration of about 100 mg based on the weight of the free base and a second administration of about 150 mg based on the weight of the free base; or

(c) a first administration of about 100 mg based on the weight of the free base and a second administration of about 200 mg based on the weight of the free base.

28. The use of any one of claims 1 to 27, wherein the compound of Formula (I) is to be administered in the free base form.

29. The use of any one of claims 1 to 28, wherein the subject is in a fed state.

30. The use of any one of claims 1 to 29, wherein the compound of Formula (I), or a pharmaceutically acceptable salt thereof, is to be administered to the subject with a meal.

31. The use of claim 30, wherein the meal is a high fat meal.

32. The use of claim 30, wherein the meal is a low fat meal.

33. The use of any one of claims 1 to 32, wherein the first administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof is with a morning meal.

34. The use of any one of claims 1 to 32, wherein the second administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof is with an evening meal.

35. The use of any one of claims 1 to 32, wherein the first administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, is with a morning meal and the second administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof is with an evening meal.

36. The use of any one of claims 1 to 35, wherein the subject is concurrently receiving a dose of a glucocorticoid.

37. The use of claim 36, wherein the glucocorticoid is selected from cortisol (hydrocortisone), cortisone, prednisone, prednisolone, methylprednisolone, dexamethasone, betamethasone, triamcinolone, fludrocortisone acetate, and deoxycorticosterone acetate.

38. The use of claim 36 or 37, wherein the glucocorticoid dose is to be measured in hydrocortisone equivalents.

39. The use of claim 36 or 37, wherein the glucocorticoid dose is to be measured as a multiple of the upper limit of normal of physiologic dosing in hydrocortisone equivalents.

40. The use of claim 36 or 37, wherein the glucocorticoid dose is a physiologic dose as measured after a time period of administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof.

41. The use of claim 36 or 37, wherein the glucocorticoid dose is a physiologic dose of about 4 to about 12 mg/m^2/day as measured after a time period of administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof.

42. The use of claim 36 or 37, wherein the glucocorticoid dose is a physiologic dose that is less than about 8 mg/m^2/day as measured after a time period of administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof.

43. The use of any one of claims 36 to 42, wherein the glucocorticoid dose of the subject is to be reduced by less than about 20% after a time period of administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, wherein the reduction of the glucocorticoid dose is relative to the glucocorticoid dose prior to administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof.

44. The use of any one of claims 36 to 42, wherein the glucocorticoid dose of the subject is to be reduced by about 20% to about 50% after a time period of administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, wherein the reduction of the glucocorticoid dose is relative to the glucocorticoid dose prior to administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof.

45. The use of any one of claims 36 to 42, wherein the glucocorticoid dose of the subject is to be reduced by greater than about 50% after a time period of administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, wherein the reduction of the glucocorticoid dose is relative to the

glucocorticoid dose prior to administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof.

46. The use of any one of claims 1 to 45, wherein the level of 17-hydroxyprogesterone is less than about 1.5 times the upper limit of normal after a time period of administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof.

47. The use of any one of claims 1 to 46, wherein the level of 17-hydroxyprogesterone is within normal limits after a time period of administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof.

48. The use of any one of claims 1 to 47, wherein the level of adrenocorticotropic hormone is less than about 1.5 times the upper limit of normal after a time period of administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof.

49. The use of any one of claims 1 to 48, wherein the level of adrenocorticotropic hormone is within normal limits after a time period of administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof.

50. The use of any one of claims 1 to 49, wherein the level of androstenedione is less than about 1.5 times the upper limit of normal after a time period of administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof.

51. The use of any one of claims 1 to 50, wherein the level of androstenedione is within normal limits after a time period of administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof.

52. The use of any one of claims 1 to 51, wherein the level of testosterone is to be reduced by at least about 25% after a time period of administration of the compound

of Formula (I), or a pharmaceutically acceptable salt thereof, wherein the reduction of the level of testosterone is relative to the level of testosterone prior to administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof.

53. The use of any one of claims 1 to 52, wherein the level of testosterone is less than about 1.5 times the upper limit of normal after a time period of administration of the pharmaceutical composition.

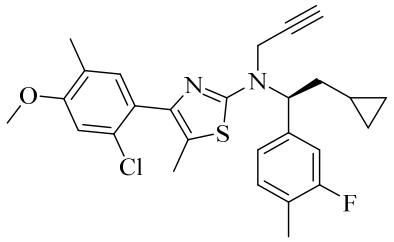
54. The use of any one of claims 1 to 53, wherein the level of testosterone is within normal limits after a time period of administration of the pharmaceutical composition comprising the compound of Formula (I), or a pharmaceutically acceptable salt thereof.

55. The use of any one of claims 36 to 54, wherein the subject exhibits a decrease in glucocorticoid burden after a time period of administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, wherein the decrease in glucocorticoid burden is relative to the glucocorticoid burden prior to administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof.

56. The use of claim 55, wherein one or more symptoms of glucocorticoid burden selected from quality of life, fatigue, sleep, insulin resistance, glucose tolerance, glucose control, dyslipidemia, hyperlipidemia, bone mineral density, bone turnover, fat mass, weight, central obesity, blood pressure, hirsutism severity, menstrual cyclicity, control of testicular adrenal rest tumor, control of ovarian adrenal rest tumor, and fertility, is improved after a time period of administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, wherein the improvement in the one or more symptoms is relative to the status of the one or more symptoms prior to administration of the compound of Formula (I), or a pharmaceutically acceptable salt thereof.

57. The use of any one of claims 40 to 56, wherein the time period of administration is at least about one year.

58. Use of a compound of Formula (I):



(I)

or a pharmaceutically acceptable thereof,

in the manufacture of a medicament for treating congenital adrenal hyperplasia in a subject, the use comprising:

selecting a subject who has a glucocorticoid dose of greater than 11 mg/m^2/day after a time period of being administered a compound of Formula (I), or a pharmaceutically acceptable thereof, at an amount of about 100 mg twice daily based on the weight of the free base;

wherein

the subject is to be administered the compound of Formula (I), or a pharmaceutically acceptable salt thereof, at a frequency of twice daily;

wherein the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, in the first administration is less than the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, in the second administration;

and wherein the amount of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, to be administered daily is greater than or equal to about 200 mg based on the weight of the free base.

59. The use of claim 58, wherein the time period of administration in step (a) is at least about one year.

60. The use of any one of claims 1 to 59, wherein the subject is female.

61. The use of any one of claims 1 to 59, wherein the subject is male.

62. The use of any one of claims 1 to 61, wherein the compound of Formula (I) is to be administed as a pharmaceutical composition comprising: (a) the compound of Formula (I), or a pharmaceutically acceptable salt thereof; and (b) one or more of an oily phase vehicle, an emulsifying agent, a nonionic surfactant, and a solubilizing agent.

63. The use of claim 62, wherein the pharmaceutical composition comprises about 1 wt% to about 20 wt% of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, based on the weight of the free base.

64. The use of claim 62, wherein the pharmaceutical composition comprises about 10 wt% of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, based on the weight of the free base.

65. The use of any one of claims 62 to 64, wherein the pharmaceutical composition comprises an oily phase vehicle.

66. The use of any one of claims 62 to 65, wherein the pharmaceutical composition comprises about 1 wt% to about 50 wt% of the oily phase vehicle.

67. The use of any one of claims 62 to 65, wherein the pharmaceutical composition comprises about 39 wt% of the oily phase vehicle.

68. The use of any one of claims 62 to 67, wherein the oily phase vehicle is selected from medium-chain triglycerides, glycerin, propylene glycol, polyethylene glycol, olive oil, soybean oil, corn oil, and transcutol.

69. The use of any one of claims 62 to 68, wherein the oily phase vehicle is medium-chain triglycerides.

70. The use of any one of claims 62 to 69, wherein the pharmaceutical composition comprises an emulsifying agent.

71. The use of any one of claims 62 to 70, wherein the pharmaceutical composition comprises about 5 wt% to about 50 wt% of the emulsifying agent.

72. The use of any one of claims 62 to 70, wherein the pharmaceutical composition comprises about 20 wt% of the emulsifying agent.

73. The use of any one of claims 62 to 72, wherein the emulsifying agent is selected from medium-chain triglycerides, propylene glycol dicaprylate/dicaprate, glycerin, propylene glycol, polyethylene glycol, olive oil, soybean oil, corn oil, and transcutol.

74. The use of any one of claims 62 to 73, wherein the emulsifying agent is propylene glycol dicaprylate/dicaprate.

75. The use of any one of claims 62 to 74, wherein the pharmaceutical composition comprises a nonionic surfactant.

76. The use of any one of claims 62 to 75, wherein the pharmaceutical composition comprises about 5 wt% to about 50 wt% of the nonionic surfactant.

77. The use of any one of claims 62 to 75, wherein the pharmaceutical composition comprises about 19 wt% of the nonionic surfactant.

78. The use of any one of claims 62 to 77, wherein the nonionic surfactant is selected from oleoyl polyoxyl-6 glycerides, linoleoyl polyoxyl-6 glycerides, Polysorbate 80, Polysorbate 20, Gelucire, lauroyl polyoxyl-32 glycerides, Poloxamer, PEG-32 stearate, and PEG-32 hydrogenated palm glycerides.

79. The use of any one of claims 62 to 78, wherein the nonionic surfactant is lauroyl polyoxyl-32 glycerides.

80. The use of any one of claims 62 to 79, wherein the pharmaceutical composition comprises a solubilizing agent.

81. The use of any one of claims 62 to 80, wherein the pharmaceutical composition comprises about 1 wt% to about 50 wt% of the solubilizing agent.

82. The use of any one of claims 62 to 80, wherein the pharmaceutical composition comprises about 11 wt% of the solubilizing agent.

83. The use of any one of claims 62 to 82, wherein the solubilizing agent is selected from oleoyl polyoxyl-6 glycerides, linoleoyl polyoxyl-6 glycerides, Polysorbate 80, Polysorbate 20, vitamin E polyethylene glycol succinate, Gelucire, lauroyl polyoxyl-32 glycerides, and Poloxamer.

84. The use of any one of claims 62 to 83, wherein the solubilizing agent is vitamin E polyethylene glycol succinate.

85. The use of claim 62, wherein the pharmaceutical composition comprises:
(a) the compound of Formula (I), or a pharmaceutically acceptable salt thereof;
(b) an oily phase vehicle;
(c) an emulsifying agent;
(d) a nonionic surfactant; and
(e) a solubilizing agent.

86. The use of claim 62, wherein the pharmaceutical composition comprises:
(a) about 5 wt% to about 15 wt% of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, based on the weight of the free base;
(b) about 35 wt% to about 45 wt% of an oily phase vehicle;
(c) about 15 wt% to about 25 wt% of an emulsifying agent;
(d) about 15 wt% to about 25 wt% of a nonionic surfactant; and
(e) about 5 wt% to about 15 wt% of a solubilizing agent.

87. The use of claim 62, wherein the pharmaceutical composition comprises:
(a) the compound of Formula (I);
(b) a medium-chain triglycerides component;

(c) a propylene glycol dicaprylate/dicaprate component;
(d) a lauroyl polyoxyl-32 glycerides component; and
(e) a vitamin E polyethylene glycol succinate component.

88. The use of claim 62, wherein the pharmaceutical composition comprises:
(a) about 5 wt% to about 15 wt% of the compound of Formula (I);
(b) about 35 wt% to about 45 wt% of medium-chain triglycerides;
(c) about 15 wt% to about 25 wt% of propylene glycol dicaprylate/dicaprate;
(d) about 15 wt% to about 25 wt% of lauroyl polyoxyl-32 glycerides; and
(e) about 5 wt% to about 15 wt% of vitamin E polyethylene glycol succinate.

89. The use of any one of claims 62 to 88, wherein the pharmaceutical composition comprises the compound of Formula (I) as a free base.

90. The use of any one of claims 62 to 89, wherein the pharmaceutical composition is formulated in unit dosage form, wherein the compound of Formula (I), or a pharmaceutically acceptable salt thereof, is present in an amount of about 5 mg to about 200 mg, based on the weight of the free base.

91. The use of claim 90, wherein the compound of Formula (I), or a pharmaceutically acceptable salt thereof, is present in the unit dosage form in an amount of about 50 mg, based on the weight of the free base.

92. The use of claim 90, wherein the compound of Formula (I), or a pharmaceutically acceptable salt thereof, is present in the unit doage form in an amount of about 100 mg, based on the weight of the free base.

93. The use of claim 90, wherein the compound of Formula (I), or a pharmaceutically acceptable salt thereof, is present in the unit dosage form in an amount of about 25 mg, based on the weight of the free base.

94. The use of any one of claims 62 to 93, wherein the pharmaceutical composition is in the form of a tablet, capsule, sachet, powder, granules, coated particle, coated tablet, enterocoated tablet, enterocoated capsule, melting strip, or melting film.

95. The use of claim 94, wherein the pharmaceutical composition is in tablet form.

96. The use of claim 94, wherein the pharmaceutical composition is in capsule form.

97. The use of any one of claims 95 to 96, wherein the tablet form or capsule form is coated.

98. The use of any one of claims 1 to 61, wherein the compound of Formula (I) is to be administered as a pharmaceutical composition in oral solution dosage form comprising:

(a) the compound of Formula (I), or a pharmaceutically acceptable salt thereof;

(b) one or more of a sweetener, an anti-oxidant, and a flavor; and

(c) a liquid vehicle.

99. The use of claim 98, wherein the pharmaceutical composition comprises:

(a) the compound of Formula (I), or a pharmaceutically acceptable salt thereof;

(b) a sweetener;

(c) an anti-oxidant;

(d) a flavor; and

(e) a liquid vehicle.

100. The use of claim 99, wherein the pharmaceutical composition further comprisies a surfactant.

101. The use of claim 98, wherein the pharmaceutical composition comprises:

(a) about 4 w/v% to about 6 w/v% of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, based on the weight of the free base;

(b) about 0.1 w/v% to about 0.2 w/v% of a sweetener;

(c) about 0.1 w/v% to about 0.2 w/v% of an anti-oxidant;

(d) about 0.05 w/v% to about 0.2 w/v% of a flavor;

(e) about 15 w/v% to about 25 w/v% of a surfactant; and

(f) about 70 w/v% to about 80 w/v% of a liquid vehicle.

102. The use of claim 98, wherein the pharmaceutical composition comprises:

(a) a compound of Formula (I), or a pharmaceutically acceptable salt thereof;

(b) saccharin;

(c) butylated hydroxytoluene;

(d) FONA orange flavor; and

(e) medium-chain triglycerides.

103. The use of claim 102, wherein the pharmaceutical composition further comprises oleoyl polyoxyl-6 glycerides.

104. The use of claim 98, wherein the pharmaceutical composition comprises:

(a) about 4 w/v% to about 6 w/v% of the compound of Formula (I), or a pharmaceutically acceptable salt thereof, based on the weight of the free base;

(b) about 0.1 w/v% to about 0.2 w/v% of saccharin;

(c) about 0.1 w/v% to about 0.2 w/v% of butylated hydroxytoluene;

(d) about 0.05 w/v% to about 0.2 w/v% of FONA orange flavor;

(e) about 15 w/v% to about 25 w/v% of oleoyl polyoxyl-6 glycerides; and

(f) about 70 w/v% to about 80 w/v% of medium-chain triglycerides.

105. The use of any one of claims 98 to 104, wherein the pharmaceutical composition comprises the compound of Formula (I) as a free base.

106. The use of any one of claims 98 to 105, wherein the pharmaceutical composition is formulated in unit dosage form, wherein the compound of Formula (I),

or a pharmaceutically acceptable salt thereof, is present in an amount of about 5 mg/mL to about 200 mg/mL, based on the weight of the free base.

107. The use of claim 106, wherein the unit dosage form comprises the compound of Formula (I), or a pharmaceutically acceptable salt thereof, in an amount of about 50 mg/mL, based on the weight of the free base.

108. The use of any one of claims 1 to 61, wherein the compound of Formula (I), or a pharmaceutically acceptable salt thereof, is to be administered in a pharmaceutical compositon comprising a spray-dried dispersion comprising:

a compound of Formula (I), or a pharmaceutically acceptable salt thereof; and

a polymer selected from a neutral polymer, an enteric polymer, and a pyrrolidone polymer;

wherein the weight ratio of the compound of Formula (I) to the polymer is from about 1:1 to about 1:9.