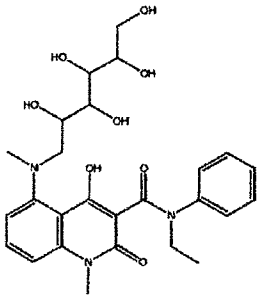
What is claimed is:

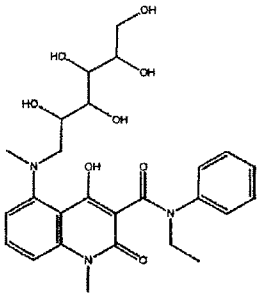
1. An isolated compound having the structure:



or a salt thereof.

2. The isolated compound of claim 1, in mono-hydrate form.

3. A composition comprising a compound having the structure:



or a salt thereof,

wherein the composition is free of laquinimod or a salt thereof.

4. The composition of claim 3, wherein the compound is in mono-hydrate form.

5. A process for preparing N-ethyl-4-hydroxyl-1-methyl-5-(methyl(2,3,4,5,6-pentahydroxyhexyl)amino)-2-oxo-N-phenyl-1,2-dihydroquinoline-3-carboxamide comprising the steps of:

a) reacting laquinimod or a salt thereof with meglumine in an aqueous solution;

b) adjusting the pH of the aqueous solution to less than 2; and

c) isolating and obtaining N-ethyl-4-hydroxyl-1-methyl-5-(methyl(2,3,4,5,6-pentahydroxyhexyl)amino)-2-oxo-N-phenyl-1,2-dihydroquinoline-3-carboxamide from the reaction mixture.

6. The process of claim 5, wherein the salt of laquinimod is a sodium salt.

7. A process for preparing N-ethyl-4-hydroxyl-1-methyl-5-(methyl(2,3,4,5,6-pentahydroxyhexyl)amino)-2-oxo-N-phenyl-1,2-dihydroquinoline-3-carboxamide comprising the steps of:

a) dissolving 5-iodo-laquinimod, meglumine and CuI in Dimethylformamide (DMF) to form a mixture;

b) removing DMF from the mixture of step a) to obtain an residue;

c) dissolving the residue of step b) in methanol to obtain a mixture;

d) adding silica gel to the mixture of step c) to obtain a suspension;

e) evaporating the suspension of step d) to dryness; and

f) isolating and obtaining N-ethyl-4-hydroxyl-1-methyl-5-(methyl(2,3,4,5,6-pentahydroxyhexyl)amino)-2-oxo-N-phenyl-1,2-dihydroquinoline-3-carboxamide from the suspension of step e).

8. The method of claim 7, wherein the mixture of step a) is stirred for 2 hours at 35-38°C prior to step b).

9. The method of claims 7 or 8, wherein step b) is achieved by DMF distillation at 2 mbar vacuum.

~~10. The method of any one of steps 7-9, wherein step f) is achieved by flash column chromatography on silica gel.~~

~~11. N-ethyl-4-hydroxyl-1-methyl-5-(methyl(2,3,4,5,6-pentahydroxyhexyl)amino)-2-oxo-N-phenyl-1,2-dihydroquinoline-3-carboxamide prepared by any one of claims 5-10.~~

~~12.~~ 10. A pharmaceutical composition comprising laquinimod or a pharmaceutically acceptable salt thereof, N-ethyl-4-hydroxyl-1-methyl-5-(methyl(2,3,4,5,6-pentahydroxyhexyl)amino)-2-oxo-N-phenyl-1,2-dihydroquinoline-3-carboxamide or a salt thereof, and at least one pharmaceutically acceptable carrier,

wherein N-ethyl-4-hydroxyl-1-methyl-5-(methyl(2,3,4,5,6-pentahydroxyhexyl)amino)-2-oxo-N-phenyl-1,2-dihydroquinoline-3-carboxamide is present in the pharmaceutical composition in an amount greater than about 0.1% w/w, relative to the amount of laquinimod, based on a determination by an HPLC method.

~~13.~~ 11. The pharmaceutical composition of claim ~~12~~ 10, wherein N-ethyl-4-hydroxyl-1-methyl-5-(methyl(2,3,4,5,6-pentahydroxyhexyl)amino)-2-oxo-N-phenyl-1,2-dihydroquinoline-3-carboxamide is present in the pharmaceutical composition in an amount greater than about 0.2% w/w, relative to the amount of laquinimod, based on a determination by an HPLC method.

~~14.~~ 12. The pharmaceutical composition of claim ~~12~~ 10 or ~~13~~ 11, wherein N-ethyl-4-hydroxyl-1-methyl-5-(methyl(2,3,4,5,6-pentahydroxyhexyl)amino)-2-oxo-N-phenyl-1,2-dihydroquinoline-3-carboxamide is present in the pharmaceutical composition in an amount not more than about

1.0%, by weight, relative to the amount of laquinimod, based on a determination by an HPLC method.

~~15.~~ The pharmaceutical composition of any one of claims 12-14, wherein the ~~pharmaceutical~~ composition is less than one week old, and the temperature during ~~the~~ less than one week did not exceed ambient temperature.

~~16. The pharmaceutical composition of any one of claims 12-15,~~ wherein the at least one ~~pharmaceutically acceptable~~ carrier is magnesium stearate.

~~17. The pharmaceutical composition of any one of claims 12-16, comprising the pharmaceutically acceptable salt of laquinimod which is a sodium salt.~~

~~18. The pharmaceutical composition of any one of claims 12-17,~~ in the form of a capsule.

~~19. The pharmaceutical composition of any one of claims 12-17,~~ in the form of a tablet.

~~20.~~ 13. A process for preparing a validated pharmaceutical composition comprising laquinimod or a pharmaceutically acceptable salt thereof, and at least one pharmaceutically acceptable carrier, comprising:

a) obtaining a batch of laquinimod or a pharmaceutically acceptable salt thereof;

b) determining the amount of N-ethyl-4-hydroxyl-1-methyl-5-(methyl(2,3,4,5,6-pentahydroxyhexyl)amino)-2-oxo-N-phenyl-1,2-dihydroquinoline-3-carboxamide in the batch using a suitable apparatus; and

c) preparing the pharmaceutical composition from the batch only if the batch is determined to have not more than about 1.0% N-ethyl-4-hydroxyl-1-methyl-5-(methyl(2,3,4,5,6-pentahydroxyhexyl)amino)-2-oxo-N-phenyl-1,2-dihydroquinoline-3-carboxamide by weight relative to the amount of laquinimod.

14.

~~21.~~ A process for preparing a packaged pharmaceutical composition comprising laquinimod or a pharmaceutically acceptable salt thereof comprising:

a) obtaining a pharmaceutical composition of laquinimod or a pharmaceutically acceptable salt thereof;

b) analyzing the pharmaceutical composition for the presence of N-ethyl-4-hydroxyl-1-methyl-5-(methyl(2,3,4,5,6-pentahydroxyhexyl)amino)-2-oxo-N-phenyl-1,2-dihydroquinoline-3-carboxamide; and

c) packaging the pharmaceutical composition in a light-resistant packaging only if the content of N-ethyl-4-hydroxyl-1-methyl-5-(methyl(2,3,4,5,6-pentahydroxyhexyl)amino)-2-oxo-N-phenyl-1,2-dihydroquinoline-3-carboxamide is not more than about 1.0% by weight relative to the amount of laquinimod.

~~22.~~ 15. A process of distributing a validated batch of a pharmaceutical composition comprising laquinimod or a pharmaceutically acceptable salt thereof and at least one pharmaceutically acceptable carrier, comprising:

a) obtaining a batch of the pharmaceutical composition;

b) performing stability testing with a sample of the batch;

c) determining the total amount of N-ethyl-4-hydroxyl-1-methyl-5-(methyl(2,3,4,5,6-pentahydroxyhexyl)amino)-2-oxo-N-phenyl-1,2-dihydroquinoline-3-carboxamide in the sample of the batch by a suitable apparatus after stability testing;

d) validating the batch for distribution only if the sample of the batch after stability testing is determined to have not more than about 1.0% by weight of N-ethyl-4-hydroxyl-1-methyl-5-(methyl(2,3,4,5,6-pentahydroxyhexyl)amino)-2-oxo-N-phenyl-1,2-dihydroquinoline-3-carboxamide relative to the amount

of laquinimod; and

e) distributing the validated batch.

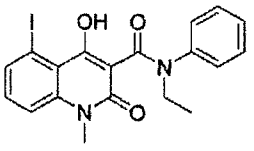
13-15

16. ~~23.~~ The process of any one of claims ~~20-22~~, wherein the pharmaceutical composition comprises the pharmaceutically acceptable salt of laquinimod which is a sodium salt.

~~24.~~ 17. N-ethyl-4-hydroxyl-1-methyl-5-(methyl(2,3,4,5,6-pentahydroxyhexyl)amino)-2-oxo-N-phenyl-1,2-dihydroquinoline-3-carboxamide or a salt thereof for use, as a reference standard to detect trace amounts of N-ethyl-4-hydroxyl-1-methyl-5-(methyl(2,3,4,5,6-pentahydroxyhexyl)amino)-2-oxo-N-phenyl-1,2-dihydroquinoline-3-carboxamide in a pharmaceutical composition comprising laquinimod or a pharmaceutically acceptable salt of laquinimod.

~~25. A method for treating a patient afflicted with multiple sclerosis comprising administering to the patient an amount of the pharmaceutical composition of any one of claims 12-19 effective to treat Multiple Sclerosis in the patient.~~

~~26.~~ 18. An isolated compound having the structure:



or a salt thereof.

~~27.~~ 19. A process for preparing a pharmaceutical composition comprising laquinimod or a pharmaceutically acceptable salt thereof comprising:

a) obtaining a batch of laquinimod or a pharmaceutically acceptable salt thereof;

b) performing stability testing with a sample from the batch;

c) determining the total amount of N-ethyl-4-hydroxyl-1-methyl-5-(methyl(2,3,4,5,6-pentahydroxyhexyl)amino)-2-oxo-N-phenyl-1,2-dihydroquinoline-3-carboxamide in the sample by a suitable apparatus after stability testing; and

d) preparing the pharmaceutical composition from the batch only if the batch is determined to have not more than about 1.0% N-ethyl-4-hydroxyl-1-methyl-5-(methyl(2,3,4,5,6-pentahydroxyhexyl)amino)-2-oxo-N-phenyl-1,2-dihydroquinoline-3-carboxamide by weight relative to the amount of laquinimod.

28. A process for preparing a packaged pharmaceutical composition comprising laquinimod or a pharmaceutically acceptable salt thereof comprising:

a) obtaining a batch of pharmaceutical composition comprising laquinimod or a pharmaceutically acceptable salt thereof;

b) performing stability testing with a sample from the batch;

c) determining the total amount of N-ethyl-4-hydroxyl-1-methyl-5-(methyl(2,3,4,5,6-pentahydroxyhexyl)amino)-2-oxo-N-phenyl-1,2-dihydroquinoline-3-carboxamide in the sample by a suitable apparatus after stability testing; and

d) packaging the pharmaceutical composition in only if the content of N-ethyl-4-hydroxyl-1-methyl-5-(methyl(2,3,4,5,6-pentahydroxyhexyl)amino)-2-oxo-N-phenyl-1,2-dihydroquinoline-3-carboxamide in the sample is determined to be not more than about 1.0% by weight relative to the amount of laquinimod.