

WHAT IS CLAIMED IS:

1. A method of treating or preventing a dyslipidemia or a disease or condition associated with a dyslipidemia, in a subject comprising administering to the subject a pharmaceutical composition comprising a C₁-C₄ alkyl ester azelate in an amount effective to treat or prevent the dyslipidemia, or a disease or condition associated with a dyslipidemia, in the subject.
2. The method of claim 1, wherein the treating or preventing comprises improving one or more abnormal lipid levels in the subject.
3. The method of claims 1-2, wherein the improving comprises lowering an elevated low density lipoprotein (LDL) level, elevating a diminished high density lipoprotein (HDL) level, lowering an elevated triglyceride level, lowering an elevated total cholesterol to HDL ratio (cholesterol/HDL), lowering an elevated LDL-to-HDL ratio (LDL/HDL), lowering an elevated LDL-to-triglyceride ratio (LDL/triglyceride), or lowering an elevated non-cholesterol HDL-to-HDL ratio (non-cholesterol HDL/HDL) in the subject.
4. The method of claims 1-3, wherein the dyslipidemia comprises at least one of the following: elevated LDL level, diminished HDL level, elevated triglyceride level, elevated cholesterol/HDL, elevated LDL/HDL, elevated LDL/triglyceride, and elevated non-cholesterol HDL/HDL.
5. The method of claims 1-4, wherein the dyslipidemia or disease or condition associated with the dyslipidemia comprises one or more of the following: hyperlipidemia, hypertriglyceridemia, hypercholesterolemia, mixed hyperlipidemia, familial combined hyperlipidemia, lipodystrophy, cardiovascular disease, hypertension, stroke, atherosclerosis, arteriosclerosis, coronary artery disease, NASH, ASH, fatty liver disease, NAFLD, hepatomegaly, pancreatitis, metabolic syndrome, insulin resistance, prediabetes, type II diabetes, overweight, and obesity.
6. The method of claims 1-5, wherein the pharmaceutical composition comprises a C₁-C₄ alkyl ester azelate selected from the group consisting of dimethyl azelate (DEA), dimethyl

azelate (DMA), di-isopropyl azelate (DiPA), di-isobutyl azelate (DiBuA), and di-2-pentyl azelate (D2PA).

7. The method of claims 1-6, wherein the pharmaceutical composition comprises a dosage of the C₁-C₄ alkyl ester azelate in a range from about 0.1 mg/kg/day to about 10 mg/kg/day.

8. The method of claims 1-7, wherein the pharmaceutical composition comprises DEA.

9. The method of claims 1-8 wherein the pharmaceutical composition comprises a dosage of DEA of about 0.1 mg/kg/day, about 0.25 mg/kg/day, about 0.5 mg/kg/day, about 1 mg/kg/day, about 2 mg/kg/day, or about 4 mg/kg/day.

10. The method of claim 1, wherein the subject has; is suspected of having; or is suspected of having a predisposition to acquiring; at least one of insulin resistance, prediabetes, type II diabetes, overweight, or obesity.

11. The method of claim 1, wherein the subject has a body mass index (BMI) from 25 to less than 30 or has a BMI of 30 or greater.

12. The method of claims 1-11, wherein the pharmaceutical composition is formulated for buccal delivery of the C₁-C₄ alkyl ester azelate.

13. The method of claims 1-11, wherein the pharmaceutical composition is formulated for gastric delivery of the C₁-C₄ alkyl ester azelate.

14. The method of claims 1-11, wherein the administering step is performed via parenteral administration.

15. The method of claims 1-11, wherein the administering step is performed via enteral administration.

16. The method of claims 1-11, wherein the administering step is performed orally, intramuscularly, subcutaneously, intravenously, or combinations thereof.

17. The method of claims 1-16, further comprising administering a second active ingredient, wherein the second active ingredient is either administered separately from the pharmaceutical composition comprising C₁-C₄ alkyl ester azelate, or is co-administered with the pharmaceutical composition comprising C₁-C₄ alkyl ester azelate.

18. The method of claims 1-17, further comprising administering a second active ingredient that is present in the pharmaceutical composition comprising the C₁-C₄ alkyl ester azelate.

19. The method of claims 1-18, wherein the second active ingredient comprises one or more of the following: a C₁-C₄ alkyl ester azelate other than DEA, a biguanide, metformin, buformin, phenformin, a thiazolidinedione, pioglitazone, rosiglitazone, a corticosteroid, prednisone, an insulin, a lipase inhibitor, orlistat, a glucagonlike peptide-1 (GLP-1) agonist, an exendin, exenatide, liraglutide, lixisenatide, albiglutide, dulaglutide, semaglutide, an HMG-CoA reductase inhibitor, a statin, atorvastatin, fluvastatin, lovastatin, pitavastatin, pravastatin, rusovastatin, simvastatin, a fibrate, gemfibrozil, fenofibrate, niacin, a leptin, a leptin agonist, metreleptin, an amylin agonist, pramlintide, and combinations thereof.

20. The method of claim 19, wherein the insulin is formulated as a rapid-acting formulation, an intermediate-acting formulation, a long-acting formulation, or combinations thereof.

21. The method of claims 1-20, wherein the pharmaceutical composition consists essentially of DEA as active ingredient.

22. The method of claims 1-20, wherein the pharmaceutical composition consists of DEA as active ingredient.

23. The method of claims 1-22, wherein the subject has insulin resistance or type II diabetes.

24. A method of treating or preventing a dyslipidemia, or a disease or condition associated with a dyslipidemia, in a subject, comprising administering to a subject an effective

amount of a pharmaceutical composition comprising DEA at a dosage range from about 0.1 mg/kg/day to about 10 mg/kg/day.

25. A method of claim 24, wherein the treating or preventing comprises improving one or more abnormal lipid levels in the subject.

26. A method of claims 24-25, wherein the improving comprises lowering an elevated LDL level, elevating a diminished HDL level, lowering an elevated triglyceride level, lowering an elevated cholesterol/HDL, lowering an elevated LDL/HDL, lowering an elevated LDL/triglyceride, or lowering an elevated non-cholesterol HDL/HDL in the subject.

27. The method of claims 24-26, further comprising administering a second active ingredient, wherein the second active ingredient is either administered separately from the pharmaceutical composition comprising DEA, or is co-administered with the pharmaceutical composition comprising DEA.

28. The method of claims 24-27, further comprising administering a second active ingredient that is present in the pharmaceutical composition comprising the DEA.

29. The method of claims 24-28, wherein the second active ingredient comprises one or more of the following: a C₁-C₄ alkyl ester azelate other than DEA, a biguanide, metformin, buformin, phenformin, a thiazolidinedione, pioglitazone, rosiglitazone, a corticosteroid, prednisone, an insulin, a lipase inhibitor, orlistat, a glucagonlike peptide-1 (GLP-1) agonist, an exendin, exenatide, liraglutide, lixisenatide, albiglutide, dulaglutide, semaglutide, an HMG-CoA reductase inhibitor, a statin, atorvastatin, fluvastatin, lovastatin, pitavastatin, pravastatin, rusovastatin, simvastatin, a fibrate, gemfibrozil, fenofibrate, niacin, a leptin, a leptin agonist, metreleptin, an amylin agonist, pramlintide, and combinations thereof.

30. The method of claims 24-29, wherein the insulin is formulated as a rapid-acting formulation, an intermediate-acting formulation, a long-acting formulation, or combinations thereof.

31. The method of claims 24-30, wherein the subject has a BMI from 25 to less than 30, or has a BMI of 30 or greater.
32. The method of claims 24-31, wherein the pharmaceutical composition is formulated for buccal delivery of the DEA.
33. The method of claims 24-31, wherein the pharmaceutical composition is formulated for gastric delivery of the DEA.
34. The method of claims 24-31, wherein the administering step is performed via parenteral administration.
35. The method of claims 24-31, wherein the administering step is performed via enteral administration.
36. The method of claims 24-31, wherein the administering step is performed intramuscularly, subcutaneously, intravenously, or combinations thereof.
37. A pharmaceutical composition comprising a C₁-C₄ alkyl ester azelate for either buccal delivery or gastric delivery, wherein the C₁-C₄ alkyl ester azelate is at a dose in a range from about 0.25 mg/mg to about 2.0 mg/kg.
38. The pharmaceutical composition of claim 37, wherein the C₁-C₄ alkyl ester azelate is selected from the group consisting of DEA, DMA, DiPA, DiBuA, and D2PA.
39. The pharmaceutical composition of claims 37-38, wherein the C₁-C₄ alkyl ester azelate is DEA.
40. The pharmaceutical composition of claims 37-39, wherein the dose is effective at improving one or more abnormal lipid levels when administered to a subject.
41. The pharmaceutical composition of claims 37-40, wherein the dose is effective at lowering an elevated LDL level, elevating a diminished HDL level, lowering an elevated triglyceride level, lowering an elevated cholesterol/HDL, lowering an elevated LDL/HDL,

lowering an elevated LDL/triglyceride, or lowering an elevated non-cholesterol HDL/HDL when administered to a subject.

42. The pharmaceutical composition of claims 37-41, wherein the dose is effective at treating or preventing a dyslipidemia, or a disease or condition associated with a dyslipidemia, when administered to a subject.

43. The pharmaceutical composition of claims 37-42, wherein the disease or condition associated with dyslipidemia is selected from the group consisting of hyperlipidemia, hypertriglyceridemia, hypercholesterolemia, mixed hyperlipidemia, familial combined hyperlipidemia, lipodystrophy, cardiovascular disease, hypertension, stroke, atherosclerosis, arteriosclerosis, coronary artery disease, NASH, ASH, fatty liver disease, NAFLD, hepatomegaly, pancreatitis, metabolic syndrome, insulin resistance, prediabetes, type II diabetes, overweight, and obesity.

44. Use of a pharmaceutical composition comprising a C₁-C₄ alkyl ester azelate for improving one or more abnormal lipid levels when administered to a subject.

45. Use according to claim 44, wherein improving one or more abnormal lipid levels comprises lowering an elevated LDL level, elevating a diminished HDL level, lowering an elevated triglyceride level, lowering an elevated cholesterol/HDL, lowering an elevated LDL/HDL, lowering an elevated LDL/triglyceride, or lowering an elevated non-cholesterol HDL/HDL when administered to a subject.

46. Use according to claims 44-45, wherein the use comprises treating or preventing a dyslipidemia or a condition or disease associated with a dyslipidemia.

47. Use according to claims 44-46, wherein the disease or condition associated with dyslipidemia is selected from the group consisting of hyperlipidemia, hypertriglyceridemia, hypercholesterolemia, mixed hyperlipidemia, familial combined hyperlipidemia, lipodystrophy, cardiovascular disease, hypertension, stroke, atherosclerosis, arteriosclerosis, coronary artery disease, NASH, ASH, fatty liver disease, NAFLD, hepatomegaly, pancreatitis, metabolic syndrome, insulin resistance, prediabetes, type II diabetes, overweight, and obesity.

48. Use according to claims 44-47, wherein the pharmaceutical composition comprises DEA.
49. Use according to claims 44-48, wherein the DEA is formulated for buccal delivery or for gastric delivery.
50. Use according to claims 44-49, wherein the DEA is administered at a dose in a range from about 0.25 mg/mg to about 2.0 mg/kg.
51. Use of a C₁-C₄ alkyl ester azelate in the manufacture of a medicament for treating or preventing a dyslipidemia or a condition or disease associated with a dyslipidemia in a subject.
52. Use according to claim 51, wherein the treating or preventing comprises improving one or more abnormal lipid levels when administered to the subject.
53. Use according to claims 51-52, wherein the treating or preventing comprises improving lowering an elevated LDL level, elevating a diminished HDL level, lowering an elevated triglyceride level, lowering an elevated cholesterol/HDL, lowering an elevated LDL/HDL, lowering an elevated LDL/triglyceride, or lowering an elevated non-cholesterol HDL/HDL when administered to the subject.
54. Use according to claims 51-53, wherein the disease or condition associated with dyslipidemia comprises one or more of the following: hyperlipidemia, hypertriglyceridemia, hypercholesterolemia, mixed hyperlipidemia, familial combined hyperlipidemia, lipodystrophy, cardiovascular disease, hypertension, stroke, atherosclerosis, arteriosclerosis, coronary artery disease, NASH, ASH, fatty liver disease, NAFLD, hepatomegaly, pancreatitis, metabolic syndrome, insulin resistance, prediabetes, type II diabetes, overweight, and obesity.
55. Use according to claims 51-54, wherein the C₁-C₄ alkyl ester azelate comprises DEA.
56. Use according to claims 51-55, wherein the DEA is formulated for buccal delivery or for gastric delivery.

57. Use according to claims 51-56, wherein the DEA is administered at a dose in a range from about 0.25 mg/mg to about 2.0 mg/kg.