CLAIMS

What is claimed is:

1. Use of ethyl eicosapentaenoate in the manufacture of a medicament for lowering triglycerides in a subject on stable statin therapy having baseline fasting triglycerides of about 200 mg/dl to less than 500 mg/dl, wherein the medicament is in a form suitable for administration of 2 g to about 4 g of ethyl eicosapentaenoate to the subject.

2. Use of ethyl eicosapentaenoate for the manufacture of a medicament for treating mixed dyslipidemia in a subject on statin therapy having baseline fasting triglycerides of about 200 mg/dl to less than 500 mg/dl, wherein the medicament is in a form suitable for administration of 2 g to about 4 g per day of ethyl eicosapentaenoate to the subject.

3. The use of claims 1 or 2 wherein the subject has a baseline serum LDL-C level of about 40 mg/dl to about 115 mg/dl.

4. The use of claim 3 wherein the medicament effects a reduction in serum LDL-C.

5. The use of claim 4, wherein the medicament effects at least a 5% reduction in LDL-C.

6. The use of claim 4, wherein the medicament effects at least a 5% reduction in fasting triglycerides and a reduction in LDL-C.

7. The use of claim 4, wherein the medicament effects at least a 10% reduction in triglycerides.

8. The use of claim 4, wherein the medicament effects at least a 15% reduction in triglycerides than the placebo controlled subject.

9. The use of claim 8, wherein the medicament effects a reduction in Apolipoprotein B, total cholesterol, and lipoprotein associated phospholipase A2.

10. The use of any one of claims 4 to 9, wherein the reduction(s) in the subject is compared to a second subject on statin therapy and having baseline fasting triglycerides of about 2000 mg/dl to less than 500 mg/dl who has not received the medicament.

11. The use of any one of claims 1 to 10, wherein the medicament is administered for a period of at least about 12 weeks.

12. The use of any one of claims 1 to 11, wherein the medicament comprises at least about 90%, by weight of all fatty acids administered, ethyl eicosapentaenoate.

13. The use of any one of claims 12, wherein the medicament comprises at least about 95%, by weight of all fatty acids administered, ethyl eicosapentaenoate.

14. The use of claim 13, wherein the medicament comprises at least about 96%, by weight of all fatty acids, ethyl eicosapentaenoate.

15. The use of any one of claims 1 to 14, wherein the subject is on stable statin therapy.

16. The use of any one of claims 1 to 15, wherein the statin is selected from the group consisting of atorvastatin, rosuvastatin and simvastatin.

17. The use of any one of claims 1 to 16, wherein the subject has a baseline body mass index not greater than 45 kg/m^2.

18. Use of a capsule comprising about 1 g of ethyl eicosapentaenoate in the manufacture for a medicament for lowering triglycerides and LDL-C in a subject on statin therapy and having fasting triglycerides of about 200 mg/dl to less than 500mg/dl, wherein about 2 to 4 capsules are to be orally administered to the subject per day.

19. Use of a capsule comprising about 1 g of ethyl eicosapentaenoate in the manufacture for a medicament for treating mixed dyslipidemia in a subject on statin therapy and having fasting triglycerides of about 200 mg/dl to less than 500mg/dl, wherein about 2 to 4 capsules are to be orally administered to the subject per day

20. The capsule of claim 18 or 19, wherein the capsule effects a reduction in fasting triglycerides and fasting LDL-C in the subject compared to fasting triglycerides and fasting LDL-C in a second subject on statin therapy who has not received the capsules.

21. The capsule of claim 20, wherein the capsule effects a reduction in fasting non-HDL-C compared to fasting non-HDL-C in the second subject.

22. The capsule of claim 20, wherein the capsule effects a reduction in fasting VLDL-C compared to fasting VLDL-C in the second subject.

23. The capsule of claim 20, wherein the capsule effects a reduction in fasting Apolipoprotein B compared to fasting Apolipoprotein B in the second subject.

24. The capsule of claim 20, wherein the capsule effects a reduction in fasting total cholesterol compared to fasting total cholesterol in the second subject.

25. The capsule of any one of claims 18 to 24, wherein the capsule comprises at least about 90%, by weight of all fatty acids present, ethyl eicosapentaenoate.

26. The capsule of claim 25, wherein the capsule comprises at least about 95%, by weight of all fatty acids present, ethyl eicosapentaenoate.

27. The capsule of any one of claims 18 to 26, wherein the capsule comprises no more than about 5%, by weight of all fatty acids present, docosahexaenoic acid or its esters.

28. The capsule of claim 27, wherein the capsule comprises no more than about 3%, by weight of all fatty acids present, docosahexaenoic acid or its esters.

29. The capsule of any one of claims 18 to 28, wherein the statin therapy is stable statin therapy.

30. The use of any one of claims 18 to 29, wherein the statin is selected from the group consisting of atorvastatin, rosuvastatin and simvastatin.

31. A composition comprising ethyl eicosapentaenoate for use in increasing plasma and/or serum EPA in a subject having baseline triglycerides of about 200 mg/dL to about 500 mg/dL and on stable statin therapy, wherein the composition comprises at least 96%, by weight, ethyl eicosapentaenoate, about 0.2% to about 0.5% by weight ethyl octadecatetraenoate, about 0.05% to about 0.25% by weight ethyl nonadecapentaenoate, about 0.2% to about 0.45% by weight ethyl arachidonate, about 0.3% to about 0.5% by weight ethyl eicosatetraenoate, about 0.05% to about 0.32% ethyl heneicosapentaenoate and not more than 0.05% ethyl-DHA, if any, and wherein the treatment comprises administering, daily, to the subject the composition in an amount sufficient to increase plasma and/or serum EPA levels in the subject by at least about 200% to compared to baseline.

32. The composition of claim 31, wherein upon administration of 2 g of the composition to the subject daily for a period of at least about 6 weeks, the subject exhibits an at least 200% increase in plasma and/or serum EPA compared to baseline.

33. The composition of claim 31, wherein upon administration of 4 g of the composition to the subject daily for a period of at least about 6 weeks, the subject exhibits an at least 300% increase in plasma and/or serum EPA compared to baseline.

34. The composition of claim 31, wherein the composition is administered in an amount sufficient to increase plasma and/or serum EPA levels in the subject by at least 300% compared to baseline.

35. The composition of claim 31, wherein the composition is administered in an amount sufficient to increase plasma and/or serum EPA levels in the subject by at least 400% compared to baseline.

36. The composition of claim 35, wherein the composition is administered to the subject daily for a period of at least about 6 weeks.

37. The composition of any one of claims 32, 33 or 34, wherein the subject has a baseline plasma and/or serum EPA level of not more than about 50 μg/ml.

38. The composition of claim 31, wherein upon daily administration of 4 g of the composition to the subject for a period of at least about 6 weeks, the subject exhibits an at least 400% increase in plasma and/or serum EPA compared to baseline.

39. The composition of claim 31, wherein upon daily administration of the composition to the subject, the subject exhibits an increase in serum and/or plasma DPA levels and a decrease in serum and/or plasma AA, DHA and/or DGLA levels.

40. The composition of claim 31, wherein upon daily administration of the composition to the subject for a period of at least 6 weeks, the subject exhibits an increase in serum and/or plasma DPA levels and a decrease in serum and/or plasma AA, DHA and/or DGLA levels compared to baseline.

41. The composition of claim 31, wherein upon daily administration of the composition to the subject for a period of at least 6 weeks, the subject exhibits a decrease in plasma and/or serum DHA levels by at least 16% compared to baseline, a decrease in DGLA plasma and/or serum levels by at least 31% compared to baseline, a decrease in AA plasma and/or serum levels by at least 20% compared to baseline, and/or an increase in plasma and/or serum DPA levels of at least 130% compared to baseline.

42. The composition of claim 31, wherein the composition comprises at least 96% by weight ethyl eicosapentaenoate, about 0.22% to about 0.4% by weight ethyl octadecatetraenoate, about 0.075% to about 0.20% by weight ethyl nonadecapentaenoate, about 0.25% to about 0.40% by weight ethyl arachidonate, about 0.3% to about 0.4% by weight ethyl eicosatetraenoate and about 0.075% to about 0.25% ethyl heneicosapentaenoate.

43. The composition of claim 31, wherein the composition comprises at least 98%, by weight, ethyl eicosapentaenoate, about 0.25% to about 0.38% by weight ethyl octadecatetraenoate, about 0.10% to about 0.15% by weight ethyl nonadecapentaenoate, about 0.25% to about 0.35% by weight ethyl arachidonate, about 0.31% to about 0.38% by weight ethyl eicosatetraenoate, and about 0.08% to about 0.20% ethyl heneicosapentaenoate.

44. The composition of claim 31, wherein the composition further comprises tocopherol in an amount of about 0.1% to about 0.3%, by weight.

45. The composition of claim 31, wherein the composition is present in a capsule shell.

46. The composition of claim 31, wherein an LDL-C level in the subject is reduced by at least about 5% compared to baseline.

CLAIMS

What is claimed is:

1. Use of ethyl eicosapentaenoate in the manufacture of a medicament for lowering triglycerides and serum LDL-C in a subject on stable statin therapy having baseline fasting triglycerides of 200 mg/dl to less than 500 mg/dl, wherein the medicament is in a form suitable for administration of 4 g of ethyl eicosapentaenoate to the subject per day.

2. Use of ethyl eicosapentaenoate for the manufacture of a medicament for treating mixed dyslipidemia in a subject on stable statin therapy having baseline fasting triglycerides of 200 mg/dl to less than 500 mg/dl, wherein the medicament is in a form suitable for administration of 4 g per day of ethyl eicosapentaenoate to the subject.

3. The use of claims 1 or 2 wherein the subject has a baseline serum LDL-C level of 40 mg/dl to 115 mg/dl.

4. The use of any one of claims 1 to 3, wherein the medicament is to be administered for a period of at least 12 weeks.

5. The use of any one of claims 1 to 4, wherein the medicament comprises at least 90%, by weight of all fatty acids administered, ethyl eicosapentaenoate.

6. The use of any one of claims 1 to 5, wherein the medicament comprises at least 95%, by weight of all fatty acids administered, ethyl eicosapentaenoate.

7. The use of any one of claims 1 to 6, wherein the medicament comprises at least 96%, by weight of all fatty acids, ethyl eicosapentaenoate.

8. The use of any one of claims 1 to 7, wherein the statin is selected from the group consisting of atorvastatin, rosuvastatin and simvastatin.

9. The use of any one of claims 1 to 8, wherein the subject has a baseline body mass index not greater than 45 kg/m^2.

10. Use of a capsule comprising about 1 g of ethyl eicosapentaenoate in the manufacture for a medicament for lowering triglycerides and LDL-C in a subject on stable statin therapy and

having fasting triglycerides of 200 mg/dl to less than 500mg/dl, wherein 4 capsules are to be orally administered to the subject per day.

11. Use of a capsule comprising about 1 g of ethyl eicosapentaenoate in the manufacture for a medicament for treating mixed dyslipidemia in a subject on stable statin therapy and having fasting triglycerides of 200 mg/dl to less than 500mg/dl, wherein 4 capsules are to be orally administered to the subject per day.

12. The use of claim 10 or 11, wherein the reduction in fasting triglycerides and fasting LDL-C in the subject is in comparison to fasting triglycerides and fasting LDL-C in a second subject on statin therapy who has not received the capsules.

13. The use of any one of claims 10 to 12, wherein the capsule comprises at least 90%, by weight of all fatty acids present, ethyl eicosapentaenoate.

14. The use of claim 13, wherein the capsule comprises at least 95%, by weight of all fatty acids present, ethyl eicosapentaenoate.

15. The use of any one of claims 10 to 14, wherein the capsule comprises no more than 5%, by weight of all fatty acids present, docosahexaenoic acid or its esters.

16. The use of claim 15, wherein the capsule comprises no more than 3%, by weight of all fatty acids present, docosahexaenoic acid or its esters.

17. The use of any one of claims 10 to 16, wherein the statin is selected from the group consisting of atorvastatin, rosuvastatin and simvastatin.

18. A composition comprising ethyl eicosapentaenoate for use in increasing plasma and/or serum EPA in a subject having baseline triglycerides of 200 mg/dL to 500 mg/dL and on stable statin therapy, wherein the composition comprises at least 96%, by weight, ethyl eicosapentaenoate, 0.2% to 0.5% by weight ethyl octadecatetraenoate, 0.05% to 0.25% by weight ethyl nonadecapentaenoate, 0.2% to 0.45% by weight ethyl arachidonate, 0.3% to 0.5% by weight ethyl eicosatetraenoate, 0.05% to 0.32% ethyl heneicosapentaenoate and not more than 0.05% ethyl-DHA, if any, and wherein the treatment comprises administering, daily, to the subject the composition in an amount sufficient to provide 4 g of the ethyl eicosapentaenoate per day.

19. The composition of claim 18, wherein the composition is administered to the subject daily for a period of at least 6 weeks.

20. The composition of claim 18, wherein the subject has a baseline plasma and/or serum EPA level of not more than 50 μg/ml.

21. The composition of claim 18, wherein the composition comprises at least 96% by weight ethyl eicosapentaenoate, 0.22% to 0.4% by weight ethyl octadecatetraenoate, 0.075% to 0.20% by weight ethyl nonadecapentaenoate, 0.25% to 0.40% by weight ethyl arachidonate, 0.3% to 0.4% by weight ethyl eicosatetraenoate and 0.075% to 0.25% ethyl heneicosapentaenoate.

22. The composition of claim 18, wherein the composition comprises at least 98%, by weight, ethyl eicosapentaenoate, 0.25% to 0.38% by weight ethyl octadecatetraenoate, 0.10% to 0.15% by weight ethyl nonadecapentaenoate, 0.25% to 0.35% by weight ethyl arachidonate, 0.31% to 0.38% by weight ethyl eicosatetraenoate, and 0.08% to 0.20% ethyl heneicosapentaenoate.

23. The composition of claim 18, wherein the composition further comprises tocopherol in an amount of 0.1% to 0.3%, by weight.

24. The composition of claim 18, wherein the composition is present in a capsule shell.