CLAIMS

What is claimed is:

1. A method of treating hypertriglyceridemia in a subject in need thereof, comprising: (a) identifying a subject having a fasting baseline triglyceride level of about 500 mg/dl to about 1500 mg/dl, and (b) administering to the subject a pharmaceutical composition comprising about 1 g to about 4 g of a pharmaceutical composition comprising at least about 96%, by weight, ethyl eicosapentaenoate, wherein the composition contains substantially no DHA or derivative thereof.

2. The method of claim 1 wherein the composition is administered to the subject 1 to 4 times per day.

3. The method of claim 1 wherein the composition is present in a capsule.

4. The method of claim 1 wherein the subject is not on concomitant lipid-altering therapy.

5. The method of claim 1 further comprising a step of measuring a baseline lipid profile in the subject prior to administering the pharmaceutical composition to said subject.

6. The method of claim 5 wherein the subject has one or more of: a baseline non-HDL-C value of about 200 mg/dl to about 300 mg/dl; a baseline total cholesterol value of about 250 mg/dl to about 300 mg/dl; a baseline vLDL-C value of about 140 mg/dl to about 200 mg/dl; and/or a baseline HDL-C value of about 10 to about 80 mg/dl.

7. The method of claim 6 wherein after administering to the subject said pharmaceutical composition daily for about 12 weeks, the subject exhibits one or more of (a) reduced triglyceride levels compared to baseline; (b) reduced Apo B levels compared to baseline; (c) increased HDL-C levels compared to baseline; (d) a reduction in non-HDL-C levels compared to baseline; and/or (e) a reduction in vLDL levels compared to baseline.

8. The method of claim 7 wherein the subject exhibits one or more of: (a) a reduction in triglyceride level of at least about 5% as compared to baseline; (b) a less than 30% increase in non-HDL-C levels or a reduction in non-HDL-C levels of at least about 1% as compared to baseline; (c) an increase in HDL-C levels of at least about 5% as compared to baseline; and/or (d) a less than 60% in LDL-C levels compared to baseline.

9. The method of claim 7 wherein the subject exhibits one or more of: (a) a reduction in triglyceride level of at least about 30% as compared to baseline; (b) no increase in non-HDL-C levels as compared to baseline; (c) no decrease in HDL-C levels compared to baseline; and/or (d) a less than 30% increase in LDL-C levels as compared to baseline.

10. The method of claim 1 wherein upon treatment the subject exhibits one or more of the following outcomes: (a) reduced triglyceride levels compared to baseline; (b) reduced Apo B levels compared to baseline; (c) increased HDL-C levels compared to baseline; (d) no increase in LDL-C levels compared to baseline; (e) a reduction in LDL-C levels compared to baseline; (f) a reduction in non-HDL-C levels compared to baseline; (g) a reduction in vLDL levels compared to baseline; (h) an increase in apo A-I levels compared to baseline; (i) an increase in apo A-I/apo B ratio compared to baseline; (j) a reduction in lipoprotein a levels compared to baseline; (k) a reduction in LDL particle number compared to baseline; (l) an increase in LDL size compared to baseline; (m) a reduction in remnant-like particle cholesterol compared to baseline; (n) a reduction in oxidized LDL compared to baseline; (o) a less than 5% change in fasting plasma glucose (FPG) compared to baseline; (p) a less than 5% change in hemoglobin A_{1c} (HbA_{1c}) compared to baseline; (q) a reduction in homeostasis model insulin resistance compared to baseline; (r) a reduction in lipoprotein associated phospholipase A2 compared to baseline; (s) a reduction in intracellular adhesion molecule compared to baseline; (t) a reduction in interleukin-6 compared to baseline; (u) a reduction in plasminogen activator inhibitor compared to baseline; (v) a reduction in high sensitivity C-reactive protein (hsCRP) compared to baseline; (w) an increase in serum phospholipid EPA compared to baseline; and/or (x) an increase in red blood cell membrane EPA compared to baseline.

11. The method of claim 1 wherein the subject is diabetic.

12. The method of claim 1 wherein the pharmaceutical composition is packaged together with instructions for using the composition to treat a cardiovascular disorder.

13. The method of claim 3, wherein the pharmaceutical composition is packaged in blister packages of about 1 to about 20 capsules per sheet.

CLAIMS

What is claimed is:

1. A composition comprising ethyl eicosapentaenoate, 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.

2. Use of ethyl eicosapentaenoate in the manufacture of a medicament for increasing serum, plasma and/or red blood cell EPA by at least about 200% compared to baseline in a subject having hypertriglyceridemia 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 nonaecapentaenoate, 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.

3. The use of claim 2 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 serum, plasma and/or red blood cell EPA compared to baseline.

4. The use of claim 2 wherein the composition is administered to the subject daily for a period of at least 6 weeks.

5. The use of claim 2 wherein the composition is administered in an amount sufficient to increase serum, plasma and/or red blood cell EPA levels in the subject by at least 400% compared to baseline.

6. The use of claim 5 wherein the composition is administered to the subject daily for a period of at least about 6 weeks.

7. The use of any one of claims 4, 5 or 8 wherein the subject has a baseline serum, plasma and/or red blood cell EPA level of not greater than about 50 μg/ml.

8. The use of claim 2 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.

9. The use of claim 2 wherein upon daily administration of the composition to the subject, the subject exhibits an increase in serum phospholipid and/or red blood cell DPA levels and a decrease in serum phospholipid and/or red blood cell arachidonic acid (AA), and/or DHA levels.

10. The use of claim 9, wherein the composition is administered to the subject daily for a period of at least about 6 weeks.

11. The use of claim 2 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 phospholipid 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 arachidonic acid (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.

12. The use of claim 2 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 nonaecapentaenoate, 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.

13. The use of claim 2 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 nonaecapentaenoate, 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.

14. The use of claim 2 wherein the composition further comprises tocopherol in an amount of 0.05% to 0.4%, by weight.

15. The use of claim 2 wherein the composition is present in a capsule shell.

16. Use of ethyl eicosapentaenoate in the manufacture of a medicament for increasing serum, plasma and/or red blood cell EPA by at least about 200% compared to baseline in a subject having a triglyceride level of at least 500 mg/dl serum triglyceride levels, wherein the medicament 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 nonaecapentaenoate, 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.

17. The use of claim 2 or claim 16, wherein an LDL-C level in the subject is reduced by at least about 5% compared to baseline.