CLAIMS

1. Use of eicosapentaenoic acid ethyl ester (E-EPA) in the manufacture of a medicament for reducing a risk of myocardial infarction, stroke, cardiovascular death, unstable angina, coronary revascularization procedures and/or unstable angina requiring hospitalization in a subject in need thereof, wherein:

the subject has elevated triglyceride levels of greater than or equal to 150 mg/dL and (1) established cardiovascular disease, or (2) diabetes and at least 1 additional risk factor for cardiovascular disease selected from: (a) is a male age 55 or older or a female age 65 or older; (b) is a cigarette smoker or was a cigarette smoker who stopped less than 3 months prior; (c) has hypertension; (d) has an HDL-C level of ≤ 40 mg/dL for men or ≤ 50 mg/dL for women; (e) has an hsCRP level of > 3.0 mg/L; (f) has renal dysfunction; (g) has retinopathy; (h) has microalbuminuria; (i) has macroalbuminuria; and/or (j) has an ankle-brachial index (ABI) of < 0.9 without symptoms of intermittent claudication,

the medicament is formulated for daily administration to provide about 4 g of E-EPA to the subject per day, and wherein,

the subject is to be administered a high intensity statin regimen comprising 40 mg to 80 mg per day of atorvastatin or 20 mg to 40 mg per day of rosuvastatin.

2. The use according to claim 1, wherein risk of occurrence of one or more components of a 3-point composite endpoint composed of cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke is reduced in the subject.

3. The use according to claim 2, wherein risk of occurrence of one or more components of the 3-point composite endpoint composed of cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke is reduced by at least about 20% in the subject.

4. The use according to claim 1, wherein risk of occurrence of one or more components of a 5-point composite endpoint composed of cardiovascular death, non-fatal stroke, non-fatal myocardial infarction, coronary revascularization, or unstable angina requiring hospitalization is reduced in the subject.

5. The use according to claim 4, wherein risk of occurrence of one or more components of the 5-point composite endpoint composed of cardiovascular death, non-

fatal myocardial infarction, non-fatal stroke, coronary revascularization, or unstable angina requiring hospitalization is reduced by at least about 20% in the subject.

6. The use according to claim 1, wherein the subject is less than about 65 years of age.

7. The use according to claim 1, wherein the subject has a fasting baseline triglyceride level of at least about 200 mg/dL and a fasting baseline high density lipoprotein-C (HDL-C) level of about 35 mg/dL or less.

8. The use according to claim 1, wherein the subject has a fasting baseline triglyceride level of 150 mg/dL to 500 mg/dL.

9. The use according to claim 1, wherein the medicament is to be administered for at least about 2 years.