CLAIMS

1. Use of a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof in the manufacture of a medicament for treating a fatty liver disease or disorder in a subject in need thereof, wherein the subject is selected to have or suspected of having a fatty liver disease or disorder, wherein the subject is non diabetic, pre- diabetic, or mildly diabetic, and wherein the medicament is to be administered into the subject in need thereof.
2. Use of a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof in the manufacture of medicament for treating a fatty liver disease or disorder in a subject in need thereof, wherein the subject is selected to have having or suspected of having a fatty liver disease or disorder, wherein
   i.the subject's serum HbA1c level is equal to or less than 6.4% or
   ii.the subject's fasting serum glucose level is equal to or less than 125 mg/dl; and
   wherein the medicament is to be administered to the subject in need thereof.
3. Use of a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof in the manufacture of a medicament for treating a fatty liver disease or disorder in a subject in need thereof,
   wherein the subject is selected to have or suspected of having a fatty liver disease or disorder, wherein
   i. the subject's serum HbA1c level is equal to or less than 6.4% or
   ii. the subject's fasting serum glucose level is equal to or less than 125 mg/dl; and
   wherein the medicament is to be administered to the subject in need thereof and administration of the medicament results in an improvement of serum EPA/AA ratio as compared to a baseline EPA/AA ratio equal to or greater than 0.4 in the subject.
4. Use of a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof in the manufacture of a medicament for treating a fatty liver disease or disorder in a subject in need thereof,
   wherein the subject is selected to have or suspected of having a fatty liver disease or disorder, wherein:
   i. the subject's serum HbA1c level is equal to or less than 6.4% or

ii. the subject's fasting serum glucose level is equal to or less than 125 mg/dl;

iii. wherein the subject is not treated with an anti-diabetic agent or has been previously treated with an anti-diabetic agent; and

wherein the medicament is to be administered to the subject in need thereof.

5. Use of a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof in combination with one or more anti-diabetic agents in the manufacture of a medicament for treating a fatty liver disease or disorder in a subject in need thereof, wherein the subject is selected to have or suspected of having a fatty liver disease or disorder, wherein

i. the subject's serum HbA1c level is equal to or less than 6.4% or

ii. the subject's fasting serum glucose level is equal to or less than 125 mg/dl; and

wherein the medicament is to be administered to the subject in need thereof.

6. Use of a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof in the manufacture of a medicament for treating a fatty liver disease or disorder in a subject in need thereof, wherein said subject is to be selected to have: :

i. NAS score greater than or equal to 3; or

ii. steatosis score equal to or greater than 1; or

iii. lobular inflammation score equal to or greater than 1; or

iv. ballooning score equal to or greater than 1; or

v. fibrosis score equal to or greater than 1;

and wherein the medicament is to be administered to the subject; and wherein the subject's serum HbA1c level is equal to or less than 6.4% or ii) the subject's fasting serum glucose level is equal to or less than 125 mg/dl.

7. Use of a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof in the manufacture of a medicament for treating a fatty liver disease or disorder in a subject in need thereof, wherein said subject is selected to have or suspected of having a fatty liver disease or disorder, wherein the subject shows a normal or substantially normal biliary function or a serum gamma glutamyl transferase (GGT) level is normal or substantially normal, and wherein said medicament is to be administered to the subject.

8. Use of a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable

amides, salts, ester or phospholipids thereof in the manufacture of a medicament for treating a fatty liver disease or disorder in a subject in need thereof, wherein the subject is selected to have or suspected of having a fatty liver disease or disorder, wherein the subject shows a normal or substantially normal biliary function or a serum gamma glutamyl transferase (GGT) level equal to or less than 33 IU/L or GGT level equal to or less than 30 IU/L for men and GGT level equal to or less than 24 IU/L for women, and wherein said medicament is to be administered to the subject.

9. Use of an effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof in the manufacture of a medicament for treating a fatty liver disease or disorder in a subject in need thereof, wherein said subject is selected to have or suspected of having a fatty liver disease or disorder, wherein the subject shows a normal or substantially normal biliary function or a serum gamma glutamyl transferase (GGT) level equal to or less than 33 IU/L,
wherein said medicament is to be administered to the subject and the subject has: ;
(a) improving the steatosis and lobular inflammation condition of said subject, and no worsening of said fibrosis stage score; and
(b) the subject exhibits the following changes in said at least one marker as compared to a baseline pretreatment level of at least 1% reduction for ALT, AST, TG, TG/HDL ratio, Free fatty acid, AA, MUFA, Palmitoleic acid, Oleic acid, Oleic acid/Stearic acid ratio, Palmitoleic acid/Palmitic acid ratio, Stearic acid/Palmitic acid ratio, y-linoleic acid/Linoleic acid ratio, Adrenic acid/AA ratio, Ferritin, Thioredoxin, TNF α, sTNF-R1, sTNF-R2, Hs-CRP, CTGF, sCD40, Leptin, complement factor D, CK18 fragment, serum HMGB1, Fas, Hyaluronic acid, Type IV collagen (7s domain), procollagen III peptide or PAI-1; at least 5% increase for EPA or EPA/AA ratio; at least 1% increase for DPA, AA/Homo-γ-linoleic acid ratio or Serum adiponectin; no worsening of ALP, bilirubin, GGT, Albumin, HDL-C, LDL-C, TC, non-HDL-C, HOMA-IR, HbA1c, Glucose, Fasting plasma glucose, postprandial plasma glucose, OGTT, platelet count or BMI.

10. Use of a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof in the manufacture of a medicament for treating a fatty liver disease or disorder in a subject in need thereof, wherein said subject is selected with at least one criteria selected from the group consisting of NAS score, steatosis score, lobular inflammation score, ballooning score and fibrosis stage is indicative of fatty liver disease; and wherein the subject shows a serum gamma glutamyl transferase (GGT) level equal to or less than 33 IU/L; and

wherein said medicament is to be administered to the subject in need thereof .

11. Use of a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof to the subject in the manufacture of a medicament for treating a fatty liver disease or disorder in a subject in need thereof, wherein the subject is selected to have:
    i. NAS score greater than or equal to 3; or
    ii. steatosis score equal to or greater than 1; or
    iii. lobular inflammation score equal to or greater than 1; or
    iv. ballooning score equal to or greater than 1; or
    v. fibrosis score equal to or greater than 1;

    wherein the subject's gamma glutamyl transferase (GGT) serum level is determined; and wherein the medicament is to be administered to the subject in need thereof if the i) shows a serum gamma glutamyl transferase (GGT) level equal to or less than 33 IU/L.
12. Use of a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof in the manufacture of a medicament for treating a fatty liver disease or disorder in a subject in need thereof, wherein the subject is selected to have or suspected of having a fatty liver disease or disorder, wherein the subject shows non or early stage hepatocyte apoptosis and wherein the medicament is to be administered to the subject.
13. Use of a therapeutically effective amount of a pharmaceutical composition comprising ethyl ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof in the manufacture of a medicament for treating a fatty liver disease or disorder in a subject in need thereof, wherein said subject is selected to have or suspected of having a fatty liver disease or disorder, wherein the subject shows non or early stage hepatocyte apoptosis or a serum soluble Fas (sFas) level equal to or less than 10.0 ng/mL and/or a serum cytokeratin-18 M30 (M30) level equal to or less than 1500 U/L or a NASH risk score equal to or less than 3.0, and wherein said medicament is to be administered to the subject in need thereof .
14. Use of an effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof in the manufacture of a medicament for treating a fatty liver disease or disorder in a subject in need thereof, wherein said subject is to be selected to have or suspected of having a fatty liver disease or disorder, wherein the subject shows non or early stage hepatocyte apoptosis or a serum soluble Fas (sFas) level equal to or

less than 10.0 ng/mL and/or a serum cytokeratin-18 M30 (M30) level equal to or less than 1500 U/L or a NASH risk score equal to or less than 3.0,

wherein said medicament is to be administered to the subject and the medicament ;

(a) improved the steatosis and lobular inflammation condition of said subject, and no worsening of said fibrosis stage score; and

(b) the subject exhibits the following changes in said at least one marker as compared to a baseline pretreatment level of at least 1% reduction for ALT, AST, TG, TG/HDL ratio, Free fatty acid, AA, MUFA, Palmitoleic acid, Oleic acid, Oleic acid/Stearic acid ratio, Palmitoleic acid/Palmitic acid ratio, Stearic acid/Palmitic acid ratio, γ-linoleic acid/Linoleic acid ratio, Adrenic acid/AA ratio, Ferritin, Thioredoxin, TNF α, sTNF-R1, sTNF-R2, Hs-CRP, CTGF, sCD40, Leptin, complement factor D, CK18 fragment, serum HMGB1, Fas, Hyaluronic acid, Type IV collagen (7s domain), procollagen III peptide or PAI-1; at least 5% increase for EPA or EPA/AA ratio; at least 1% increase for DPA, AA/Homo-γ-linoleic acid ratio or Serum adiponectin; no worsening of ALP, bilirubin, GGT, Albumin, HDL-C, LDL-C, TC, non-HDL-C, HOMA-IR, HbA1c, Glucose, Fasting plasma glucose, postprandial plasma glucose, OGTT, platelet count, M30, sFas, NASH risk score or BMI.

15. Use of a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof in the manufacture of a medicament for treating a fatty liver disease or disorder in a subject in need thereof, wherein said subject is selected with at least one criteria selected from the group consisting of NAS score, steatosis score, lobular inflammation score, ballooning score and fibrosis stage is indicative of fatty liver disease; and wherein the subject shows non or early stage hepatocyte apoptosis or a serum soluble Fas (sFas) level equal to or less than 10.0 ng/mL and/or a serum cytokeratin-18 M30 (M30) level equal to or less than 1500 U/L or a NASH risk score equal to or less than 3.0; and

wherein said medicament is to be administered to the subject in need thereof.

16. Use of a therapeutically effective amount of a pharmaceutical composition comprising ethyl ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof to the subject in the manufacture of a medicament for treating a fatty liver disease or disorder in a subject in need thereof, wherein said subject is selected to have:
    i. NAS score greater than or equal to 3; or
    ii. steatosis score equal to or greater than 1; or
    iii. lobular inflammation score equal to or greater than 1; or
    iv. ballooning score equal to or greater than 1; or

v. fibrosis score equal to or greater than 1;

wherein the subject's soluble Fas (sFas) serum level and/or serum cytokeratin-18 M30 (M30) level or NASH risk score is determined; and

(a) wherein the medicament is to be administered to the subject if the i) shows a sFas level equal to or less than 10.0 ng/mL and/or M30 level equal to or less than 1500 U/L or a NASH risk score equal to or less than 3.0.

17. The use of any of claims 5, wherein the anti-diabetic agent is selected from the following group: PPARγ agonists, biguanides, protein tyrosine phosphatase-1B (PTP-1B) inhibitors, meglitinides, α glucoside hydrolase inhibitors, insulin secreatagogues, A2 antagonists, insulin and related compounds, PPAR dual agonists, SGLT2 inhibitors, GSK 3β/GSK 3 inhibitors, dipeptidyl peptidase IV (DP-IV) inhibitors, peptides, sulfonylureas, and nonsulfonylurea secretagogues.
18. The use of any of claims 1-16, wherein the fatty liver disease or disorder is selected from the group consisting of Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steatohepatits (NASH).
19. The use of any of claims 1-16, wherein selection of a subject having or suspected of having a fatty liver disease or disorder comprises selecting a subject having a score selected from the group consisting of: a NAS score greater than or equal to 3, a steatosis score equal to or greater than 1, a lobular inflammation score equal to or greater than 1, a ballooning score equal to or greater than 1 and a fibrosis score equal to or greater than 1.
20. The use of any of claims 1-16, wherein fatty liver disease is characterized by the baseline pretreatment level in the subject of at least one criteria selected from the group consisting of ALT in a range of 10 to 300 IU/L, AST in a range of 10 to 250 IU/L, HDL/C in a range of 25 to 55 mg/dl, LDL-C in a range of 100 to 200 mg/dl, triglycerides in a range of 100 to 1000 mg/dl, TC in a range of 170 to 300 mg/dl, High TG and low HDL-C, TG/HDL-C ratio in a range of 3.75 to 10, non-HDL-C in a range of 100 to 250 mg/dl, Free fatty acid in a range of 400 to 1000 μ Eq/L, HOMA-IR in a range of 1.5 to 5, HbA1c in a range of 5.7 to 10%, Fasting plasma glucose in a range of 100 to 200 mg/dl, impaired glucose tolerance and metabolic syndrome.
21. The use of any of claims 1-16, wherein a therapeutically effective amount of EPA-E to be administered to the subject is an amount between about 1800 and about 2700 mg per day.
22. The use of any of claims 1-16, wherein a therapeutically effective amount of EPA-E to be administered to the subject is at least 1800 mg per day.
23. The use of any of claims 1-16, wherein a therapeutically effective amount of EPA-E to be administered to the subject is at least 2700 mg per day.

24. The use of any of claims 1-16, wherein said reduced ALT value is at least 5% lower than said baseline ALT value and/or said reduced AST value is at least 5% lower than said baseline AST value.
25. The use of any of claims 1-16, wherein after administration of ethyl eicosapentanoate for at least 3 months, said subject exhibits the following changes in said at least one marker as compared to the baseline level of at least 1% reduction for ALT, AST, TG, TG/HDL ratio, Free fatty acid, AA, MUFA, Palmitoleic acid, Oleic acid, Oleic acid/Stearic acid ratio, Palmitoleic acid/Palmitic acid ratio, Adrenic acid/AA ratio, Ferritin, Thioredoxin, TNF α, sTNF-R1, sTNF-R2, Hs-CRP, CRGF, sCD40, Leptin, complement factor D, CK18 fragment, serum HMGB1, Fas, Hyaluronic acid, Type IV collagen (7s domain), procollagen III peptide or PAI-1; at least 5% increase for EPA or EPA/AA ratio; at least 1% increase for DPA, AA/Homo-γ-linoleic acid ratio or Serum adiponectin; no worsening of ALP, bilirubin, GGT, Albumin, HDL-C, LDL-C, TC, non-HDL-C, HOMA-IR, HbA1c, Glucose, Fasting plasma glucose, postprandial plasma glucose, OGTT, platelet count or BMI.
26. The use of claims 1, 2, 4, 5, 6, or13-16, further comprising an improvement in serum EPA/AA ratio as compared to a baseline EPA/AA ratio.
27. The use of claim26, wherein the improvement in serum EPA/AA ratio as compared to a baseline EPA/AA ratio is equal to or greater than 0.4.
28. The use of any of claims 1-16, wherein the medicament comprises a self-emulsifying composition comprising 50 to 95% by weight, a omega-3 polyunsaturated fatty acid or a pharmaceutically acceptable amide, salt, phospholipid or ester thereof.
29. The use of any of claims 1-16, wherein the medicament comprises a self-emulsifying composition comprising 50 to 95% by weight, of EPA-E, EPA or pharmaceutically acceptable amides, salts, esters or phospholipids thereof.
30. The use of any of claims 1-16, wherein the medicament comprises 5 to 50% by weight of an emulsifier having a hydrophilic lipophilic balance of at least 10.
31. The use of any of claims30, wherein the medicament comprises ethanol content up to 4% by weight in relation to the total content of the compound and the emulsifier.
32. The use of any of claims30, wherein the emulsifier is at least one member selected from the group consisting of polyoxyethylene hydrogenated castor oil, polyoxyethylene sorbitan fatty acid ester, polyoxyethylene castor oil, polyethylene glycol fatty acid ester, polyoxyethylene polyoxypropylene glycol, sucrose fatty acid ester, sorbitan fatty acid ester, glycerin fatty acid ester and lecithin.
33. The use of any of claims30, wherein the medicament contains a lecithin.
34. The use of any of claims 30, wherein the medicament contains a polyhydric alcohol.

35. The use of any of claims 16, wherein the medicament contains at least one member selected from the group consisting of eicosapentaenoic acid, docosahexaenoic acid, and their pharmaceutically acceptable amides, salts, esters and phospholipids.
36. The use of any of claims 1-16, wherein EPA-E, EPA or pharmaceutically acceptable amides, salts, esters or phospholipids thereof present in the medicament is at least 40% by weight in total of the fatty acids and derivatives.
37. The use of any of claims 1-160, wherein the medicament is Epadel™, Lovaza™, Omacor ™, Lotriga™ or Vascepa ™.

CLAIMS

1. A method for treating a fatty liver disease or disorder in a subject in need thereof, comprising:

    a. selecting a subject having or suspected of having a fatty liver disease or disorder, wherein the subject is non diabetic, pre- diabetic, or mildly diabetic; and

b. administering a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof.

2. A method for treating a fatty liver disease or disorder in a subject in need thereof, comprising:

    a. selecting a subject having or suspected of having a fatty liver disease or disorder, wherein

        i. the subject's serum HbA1c level is equal to or less than 6.4% or

ii. the subject's fasting serum glucose level is equal to or less than 125 mg/dl; and

b. administering a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof.

3. A method for treating a fatty liver disease or disorder in a subject in need thereof, comprising:

a. selecting a subject having or suspected of having a fatty liver disease or disorder, wherein

i. the subject's serum HbA1c level is equal to or less than 6.4% or

ii. the subject's fasting serum glucose level is equal to or less than 125 mg/dl; and

b. administering a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof; and

c. administering in step b results in an improvement of serum EPA/AA ratio as compared to a baseline EPA/AA ratio equal to or greater than 0.4 in the subject.

4. A method for treating a fatty liver disease or disorder in a subject in need thereof, comprising:

a. selecting a subject having or suspected of having a fatty liver disease or disorder, wherein

i. the subject's serum HbA1c level is equal to or less than 6.4% or

ii. the subject's fasting serum glucose level is equal to or less than 125 mg/dl;

iii. wherein the subject is not treated with an anti-diabetic agent or has been previously treated with an anti-diabetic agent; and

b. administering a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof.

5. A method for treating a fatty liver disease or disorder in a subject in need thereof, comprising:

a. selecting a subject having or suspected of having a fatty liver disease or disorder, wherein

i. the subject's serum HbA1c level is equal to or less than 6.4% or

ii. the subject's fasting serum glucose level is equal to or less than 125 mg/dl; and

b. administering a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof in combination with one or more anti-diabetic agents.

6. A method for treating a fatty liver disease or disorder in a subject in need thereof, comprising:

(a) selecting a subject having a:

i. NAS score greater than or equal to 3; or

ii. steatosis score equal to or greater than 1; or

iii. lobular inflammation score equal to or greater than 1; or

iv. ballooning score equal to or greater than 1; or

v. fibrosis score equal to or greater than 1;

(b) administering a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof to the subject; and wherein the subject's serum HbA1c level is equal to or less than 6.4% or ii) the subject's fasting serum glucose level is equal to or less than 125 mg/dl.

7. The method of any of claims 1-6, wherein the subject is non diabetic.

8. The method of any of claims 1-6, wherein the subject is pre-diabetic.

9. The method of any of claims 1-6, wherein the subject is mildly diabetic.

10. A method for treating a fatty liver disease or disorder in a subject in need thereof, comprising: selecting a subject having or suspected of having a fatty liver disease or disorder, wherein the subject shows a normal or substantially normal biliary function or a serum gamma glutamyl transferase (GGT) level is normal or substantially normal, and administering a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof.

11. A method for treating a fatty liver disease or disorder in a subject in need thereof, comprising: selecting a subject having or suspected of having a fatty liver disease or disorder,

wherein the subject shows a normal or substantially normal biliary function or a serum gamma glutamyl transferase (GGT) level equal to or less than 78 IU/L or GGT level equal to or less than 85 IU/L for men and GGT level equal to or less than 55 IU/L for women.

12. A method for treating a fatty liver disease or disorder in a subject in need thereof, comprising: selecting a subject having or suspected of having a fatty liver disease or disorder, wherein the subject shows a normal or substantially normal biliary function or a serum gamma glutamyl transferase (GGT) level equal to or less than 33 IU/L or GGT level equal to or less than 30 IU/L for men and GGT level equal to or less than 24 IU/L for women, and administering a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof.

13. A method for treating a fatty liver disease or disorder in a subject in need thereof, comprising: selecting a subject having or suspected of having a fatty liver disease or disorder, wherein the subject shows a normal or substantially normal biliary function or a serum gamma glutamyl transferase (GGT) level equal to or less than 33 IU/L,

(a) administering to a subject an effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof;

(b) improving the steatosis and lobular inflammation condition of said subject, and no worsening of said fibrosis stage score; and

(c) the subject exhibits the following changes in said at least one marker as compared to a baseline pretreatment level of at least 1% reduction for ALT, AST, TG, TG/HDL ratio, Free

fatty acid, AA, MUFA, Palmitoleic acid, Oleic acid, Oleic acid/Stearic acid ratio, Palmitoleic acid/Palmitic acid ratio, Stearic acid/Palmitic acid ratio, y-linoleic acid/Linoleic acid ratio, Adrenic acid/AA ratio, Ferritin, Thioredoxin, TNF α, sTNF-R1, sTNF-R2, Hs-CRP, CTGF, sCD40, Leptin, complement factor D, CK18 fragment, serum HMGB1, Fas, Hyaluronic acid, Type IV collagen (7s domain), procollagen III peptide or PAI-1; at least 5% increase for EPA or EPA/AA ratio; at least 1% increase for DPA, AA/Homo-γ-linoleic acid ratio or Serum adiponectin; no worsening of ALP, bilirubin, GGT, Albumin, HDL-C, LDL-C, TC, non-HDL-C, HOMA-IR, HbA1c, Glucose, Fasting plasma glucose, postprandial plasma glucose, OGTT, platelet count or BMI.

14. A method for treating a fatty liver disease or disorder in a subject in need thereof, comprising:

(a) selecting a subject where at least one criteria selected from the group consisting of NAS score, steatosis score, lobular inflammation score, ballooning score and fibrosis stage is indicative of fatty liver disease; and wherein the subject shows a serum gamma glutamyl transferase (GGT) level equal to or less than 33 IU/L; and

(b) administering a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof.

15. A method for treating a fatty liver disease or disorder in a subject in need thereof, comprising:

(a) selecting a subject having a:

vi. NAS score greater than or equal to 3; or

vii. steatosis score equal to or greater than 1; or

viii. lobular inflammation score equal to or greater than 1; or

ix. ballooning score equal to or greater than 1; or

x. fibrosis score equal to or greater than 1;

(b) determining the subject's gamma glutamyl transferase (GGT) serum level; and

(c) administering a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof to the subject, if the i) shows a serum gamma glutamyl transferase (GGT) level equal to or less than 33 IU/L.

16. A method for treating a fatty liver disease or disorder in a subject in need thereof, comprising: selecting a subject having or suspected of having a fatty liver disease or disorder, wherein the subject shows non or early stage hepatocyte apoptosis and administering to the subject a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof.

17. A method for treating a fatty liver disease or disorder in a subject in need thereof, comprising: selecting a subject having or suspected of having a fatty liver disease or disorder, wherein the subject shows non or early stage hepatocyte apoptosis or a serum soluble Fas (sFas) level equal to or less than 10.0 ng/mL and/or a serum cytokeratin-18 M30 (M30) level equal to or less than 1500 U/L or a NASH risk score equal to or less than 3.0, and

administering a therapeutically effective amount of a pharmaceutical composition comprising ethyl ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof.

18. A method for treating a fatty liver disease or disorder in a subject in need thereof, comprising: selecting a subject having or suspected of having a fatty liver disease or disorder, wherein the subject shows non or early stage hepatocyte apoptosis or a serum soluble Fas (sFas) level equal to or less than 10.0 ng/mL and/or a serum cytokeratin-18 M30 (M30) level equal to or less than 1500 U/L or a NASH risk score equal to or less than 3.0,

(a) administering to a subject an effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof;

(b) improving the steatosis and lobular inflammation condition of said subject, and no worsening of said fibrosis stage score; and

(c) the subject exhibits the following changes in said at least one marker as compared to a baseline pretreatment level of at least 1% reduction for ALT, AST, TG, TG/HDL ratio, Free fatty acid, AA, MUFA, Palmitoleic acid, Oleic acid, Oleic acid/Stearic acid ratio, Palmitoleic acid/Palmitic acid ratio, Stearic acid/Palmitic acid ratio, γ-linoleic acid/Linoleic acid ratio, Adrenic acid/AA ratio, Ferritin, Thioredoxin, TNF α, sTNF-R1, sTNF-R2, Hs-CRP, CTGF, sCD40, Leptin, complement factor D, CK18 fragment, serum HMGB1, Fas, Hyaluronic acid, Type IV collagen (7s domain), procollagen III peptide or PAI-1; at least 5% increase for EPA or EPA/AA ratio; at least 1% increase for DPA, AA/Homo-γ-linoleic acid ratio or Serum adiponectin; no worsening of ALP, bilirubin, GGT, Albumin, HDL-C, LDL-C, TC, non-HDL-C, HOMA-IR, HbA1c, Glucose, Fasting plasma glucose, postprandial plasma glucose,

OGTT, platelet count, M30, sFas, NASH risk score or BMI.

19. A method for treating a fatty liver disease or disorder in a subject in need thereof, comprising:

(a) selecting a subject where at least one criteria selected from the group consisting of NAS score, steatosis score, lobular inflammation score, ballooning score and fibrosis stage is indicative of fatty liver disease; and wherein the subject shows non or early stage hepatocyte apoptosis or a serum soluble Fas (sFas) level equal to or less than 10.0 ng/mL and/or a serum cytokeratin-18 M30 (M30) level equal to or less than 1500 U/L or a NASH risk score equal to or less than 3.0; and

(b) administering a therapeutically effective amount of a pharmaceutical composition comprising ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof.

20. A method for treating a fatty liver disease or disorder in a subject in need thereof, comprising:

(a) selecting a subject having a:

xi. NAS score greater than or equal to 3; or

xii. steatosis score equal to or greater than 1; or

xiii. lobular inflammation score equal to or greater than 1; or

xiv. ballooning score equal to or greater than 1; or

xv. fibrosis score equal to or greater than 1;

(b) determining the subject's soluble Fas (sFas) serum level and/or serum cytokeratin-18 M30 (M30) level or NASH risk score; and

(c) administering a therapeutically effective amount of a pharmaceutical composition comprising ethyl ethyl eicosapentanoate (EPA-E), eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof to the subject, if the i) shows a sFas level equal to or less than 10.0 ng/mL and/or M30 level equal to or less than 1500 U/L or a NASH risk score equal to or less than 3.0.

21. The method of any of claims 1-20, wherein the subject receives no treatment for diabetes or no anti-diabetic agent.

22. The method of any of claims 1-20, wherein the subject receives at least one treatment for diabetes or at least one anti-diabetic agent.

23. The method of any of claims 1-20, wherein the subject receives at least one treatment for diabetes or at least one anti-diabetic agent is administered simultaneously with the pharmaceutical composition.

24. The method of any of claims 1-20, wherein the anti-diabetic agent is selected from the following group: PPARγ agonists, biguanides, protein tyrosine phosphatase-1B (PTP-1B) inhibitors, meglitinides, α glucoside hydrolase inhibitors, insulin secreatagogues, A2 antagonists, insulin and related compounds, PPAR dual agonists, SGLT2 inhibitors, GSK 3β/GSK 3 inhibitors, dipeptidyl peptidase IV (DP-IV) inhibitors, peptides, sulfonylureas, and nonsulfonylurea secretagogues.

25. The method of any of claims 1-20, wherein the subject consumes a diabetic diet.

26. The method of any of claims 1-20, wherein the subject consumes a western diet.

27. The method of any of claims 1-20, wherein the fatty liver disease or disorder is selected from the group consisting of Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steatohepatits (NASH).

28. The method of any of claims 1-20, wherein selecting a subject having or suspected of having a fatty liver disease or disorder comprises selecting a subject having a score selected from the group consisting of: a NAS score greater than or equal to 3, a steatosis score equal to or greater than 1, a lobular inflammation score equal to or greater than 1, a ballooning score equal to or greater than 1 and a fibrosis score equal to or greater than 1.

29. The method of any of claims 1-20, wherein selecting a subject having or suspected of having a fatty liver disease or disorder comprises selecting a subject who is overweight.

30. The method of claim 29, wherein selecting a subject having or suspected of having a fatty liver disease or disorder further comprises selecting a subject with a body mass index (BMI) greater than or equal to 25 kg/m^2.

31. The method of any of claims 1-20, wherein selecting a subject having or suspected of having a fatty liver disease or disorder further comprises selecting a subject with a familial history of fatty liver disease.

32. The method of any of claims 1-20, wherein selecting a subject having or suspected of having a fatty liver disease or disorder comprises selecting a subject with a NAS score greater than or equal to 4.

33. The method of any of claims 1-20, wherein the subject is characterized by at least one criteria selected from the group consisting of a baseline ALT value of about 10 to about 300 IU/L; a baseline AST value of about 10 to about 250 IU/L; a baseline steatosis grade of about 2 to 3; and a baseline lobular inflammation grade of about 2 to 3.

34. A method of any of claims 1-20, wherein fatty liver disease is characterized by the baseline pretreatment level in the subject of at least one criteria selected from the group consisting of ALT in a range of 10 to 300 IU/L, AST in a range of 10 to 250 IU/L, HDL/C in a range of 25 to 55 mg/dl, LDL-C in a range of 100 to 200 mg/dl, triglycerides in a range of 100 to 1000 mg/dl, TC in a range of 170 to 300 mg/dl, High TG and low HDL-C, TG/HDL-C ratio in a range of 3.75 to 10, non-HDL-C in a range of 100 to 250 mg/dl, Free fatty acid in a range of 400 to 1000 μ Eq/L, HOMA-IR in a range of 1.5 to 5, HbA1c in a range of 5.7 to 10%, Fasting plasma glucose in a range of 100 to 200 mg/dl, impaired glucose tolerance and metabolic syndrome.

35. A method of any of claims 1-20, wherein fatty liver disease is characterized by the baseline pretreatment level in the subject of at least one criteria selected from the group consisting of low level of EPA, DPA, DHA, EPA/AA, DHA/AA. DHA/DPA, AA/Homo-γ-linoleic acid: and high level of AA, MUFA, Palmitoleic acid, Oleic acid, Oleic acid/Stearic acid, Palmitoleic acid/Palmitic acid, γ-linoleic acid/Linoleic acid, Adrenic acid/AA compared to each average level in subjects with fatty liver disease.

36. The method of any of claims 1-20, wherein after said administration of said EPA-E, eicosapentaenoic acid (EPA), or pharmaceutically acceptable amides, salts, ester or phospholipids thereof for about one year, said subject exhibits at least one improvement selected from the group consisting of a reduced ALT value as compared to said baseline ALT

value; a reduced AST value as compared to said baseline AST value; a reduced steatosis grade as compared to said baseline steatosis grade; and a reduced lobular inflammation grade as compared to said baseline lobular inflammation grade.

37. The method of any of claims 1-20, wherein a therapeutically effective amount of EPA-E administered to the subject is an amount between about 1800 and about 2700 mg per day.

38. The method of any of claims 1-20, wherein a therapeutically effective amount of EPA-E administered to the subject is at least 1800 mg per day.

39. The method of any of claims 1-20, wherein a therapeutically effective amount of EPA-E administered to the subject is at least 2700 mg per day.

40. The method of any of claims 1-20, wherein the subject is further characterized by having at least one condition selected from the group consisting of high triglycerides and low HDL-C, impaired glucose tolerance and metabolic syndrome.

41. The method of any of claims 1-20, wherein said reduced ALT value is at least 5% lower than said baseline ALT value and/or said reduced AST value is at least 5% lower than said baseline AST value.

42. The method of any of claims 1-20, further comprising determining in said subject prior to treatment a baseline level in serum of at least one member selected from the group consisting of ALT in a range of 10 to 300 IU/L, AST in a range of 10 to 250 IU/L, HDL-C in a range of 25 to 55 mg/dl, LDL-C in a range of 100 to 200 mg/dl, triglycerides in a range of 100 to 1000 mg/dl, TC in a range of 170 to 300 mg/dl, High TG and low HDL-C, TG/HDL-C ratio in a range of 3.75 to 10, non-HDL-C in a range of 100 to 250 mg/dl, Free fatty acid in a range of

400 to 1000 μ Eq/L, HOMA-IR in a range of 1.5 to 5, HbA1c in a range of 5.7 to 10%, Fasting plasma glucose in a range of 100 to 200 mg/dl.

43. The method of any of claims 1-20, wherein after administration of ethyl eicosapentanoate for at least 3 months, said subject exhibits the following changes in said at least one marker as compared to the baseline level of at least 1% reduction for ALT, AST, TG, TG/HDL ratio, Free fatty acid, AA, MUFA, Palmitoleic acid, Oleic acid, Oleic acid/Stearic acid ratio, Palmitoleic acid/Palmitic acid ratio, Adrenic acid/AA ratio, Ferritin, Thioredoxin, TNF α, sTNF-R1, sTNF-R2, Hs-CRP, CRGF, sCD40, Leptin, complement factor D, CK18 fragment, serum HMGB1, Fas, Hyaluronic acid, Type IV collagen (7s domain), procollagen III peptide or PAI-1; at least 5% increase for EPA or EPA/AA ratio; at least 1% increase for DPA, AA/Homo-γ-linoleic acid ratio or Serum adiponectin; no worsening of ALP, bilirubin, GGT, Albumin, HDL-C, LDL-C, TC, non-HDL-C, HOMA-IR, HbA1c, Glucose, Fasting plasma glucose, postprandial plasma glucose, OGTT, platelet count or BMI.

44. The method of any of claims 1-20, further comprising improving the steatosis and lobular inflammation condition of said subject, and no worsening of said fibrosis stage score.

45. The method of any of claims 1-20, further comprising: improving the NAS score in said subject (i) to a composite score of ≦3 and no worsening of said fibrosis stage score, or (ii) by ≧2 across at least two of the NAS components and no worsening of said fibrosis stage score.

46. The method of claims 1, 2, 4, 5, 6, or 14-20, further comprising an improvement in serum EPA/AA ratio as compared to a baseline EPA/AA ratio.

47. The method of claim 46, wherein the improvement in serum EPA/AA ratio as compared to a baseline EPA/AA ratio is equal to or greater than 0.4.

48. The method of any of claims 1-20 wherein the pharmaceutical composition is administered to the subject 1 to 4 times per day.

49. The method of any of claims 1-20, wherein the composition is present in one or more capsules.

50. The method of any of claims 1-20, wherein the composition comprises a self-emulsifying composition comprising 50 to 95% by weight, a omega-3 polyunsaturated fatty acid or a pharmaceutically acceptable amide, salt, phospholipid or ester thereof.

51. The method of any of claims 1-20, wherein the composition comprises a self-emulsifying composition comprising 50 to 95% by weight, of EPA-E, EPA or pharmaceutically acceptable amides, salts, esters or phospholipids thereof.

52. The method of claim 51, wherein the composition comprises a self-emulsifying composition comprising at least 60%, by weight, of EPA-E, EPA or pharmaceutically acceptable amides, salts, esters or phospholipids thereof.

53. The method of claim 51, wherein the composition comprises a self-emulsifying composition comprising at least 70%, by weight, of EPA-E, EPA or pharmaceutically acceptable amides, salts, esters or phospholipids thereof.

54. The method of claim 51, wherein the composition comprises a self-emulsifying composition comprising at least 80%, by weight, of EPA-E, EPA or pharmaceutically acceptable amides, salts, esters or phospholipids thereof.

55. The method of claim 51, wherein the composition comprises a self-emulsifying composition comprising at least 90%, by weight, of EPA-E, EPA or pharmaceutically acceptable amides, salts, esters or phospholipids thereof.

56. The method of claim 51, wherein the composition comprises a self-emulsifying composition comprising at least 95%, by weight, of EPA-E, EPA or pharmaceutically acceptable amides, salts, esters or phospholipids thereof.

57. The method of claim 51, wherein the composition comprises a self-emulsifying composition comprising at least 96%, by weight, of EPA-E, EPA or pharmaceutically acceptable amides, salts, esters or phospholipids thereof.

58. The method of any of claims 1-20, wherein the composition comprises 5 to 50% by weight of an emulsifier having a hydrophilic lipophilic balance of at least 10.

59. The method of any of claims 1-20, wherein the composition comprises 10 to 50% by weight of an emulsifier having a hydrophilic lipophilic balance of at least 10.

60. The method of any of claims 1-20, wherein the composition comprises 20 to 50% by weight of an emulsifier having a hydrophilic lipophilic balance of at least 10.

61. The method of any of claims 1-20, wherein the composition comprises 30 to 50% by weight of an emulsifier having a hydrophilic lipophilic balance of at least 10.

62. The method of any of claims 1-20, wherein the composition comprises 40 to 50% by weight of an emulsifier having a hydrophilic lipophilic balance of at least 10.

63. The method of any of claims 1-20, wherein the composition comprises ethanol content up to 4% by weight in relation to the total content of the compound and the emulsifier.

64. The method of any of claims 1-20, wherein the composition does not contain ethanol.

65. The method of any of claims 58-64, wherein the emulsifier is at least one member selected from the group consisting of polyoxyethylene hydrogenated castor oil, polyoxyethylene sorbitan fatty acid ester, polyoxyethylene castor oil, polyethylene glycol fatty acid ester, polyoxyethylene polyoxypropylene glycol, sucrose fatty acid ester, sorbitan fatty acid ester, glycerin fatty acid ester and lecithin.

66. The method of any of claims 58-64, wherein the emulsifier is at least one member selected from the group consisting of polyoxyethylene hydrogenated castor oil, polyoxyethylene sorbitan fatty acid ester, polyoxyethylene castor oil, sucrose fatty acid ester, sorbitan fatty acid ester and glycerin fatty acid ester.

67. The method of claim 66, wherein the polyoxyethylene hydrogenated castor oil is at least one member selected from the group consisting of polyoxyethylene (20) hydrogenated castor oil, polyoxyethylene (40) hydrogenated castor oil, polyoxyethylene (50) hydrogenated castor oil, polyoxyethylene (60) hydrogenated castor oil, and polyoxyethylene (100) hydrogenated castor oil.

68. The method of claim 66, wherein the polyoxyethylene sorbitan fatty acid ester is at least one member selected from the group consisting of polyoxyethylene sorbitan monooleate, polyoxyethylene sorbitan tristearate, polyoxyethylene sorbitan monostearate, polyoxyethylene sorbitan monopalmitate, and polyoxyethylene sorbitan monolaurate.

69. The method of claim 66, wherein the sucrose fatty acid ester is at least one member selected from the group consisting of sucrose laurate, sucrose myristate, sucrose palmitate, sucrose stearate, and sucrose oleate.

70. The method of any of claims 1-20, wherein the composition contains a lecithin.

71. The method of claim 70, wherein the lecithin is at least one member selected from the group consisting of soybean lecithin, enzymatically decomposed soybean lecithin, hydrogenated soybean lecithin, and egg yolk lecithin.

72. The method of any of claims 1-20, wherein the composition contains a polyhydric alcohol.

73. The method of claim 72, wherein the polyhydric alcohol is propylene glycol or glycerin.

74. The method of any of claims 1-20, wherein the composition contains at least one member selected from the group consisting of eicosapentaenoic acid, docosahexaenoic acid, and their pharmaceutically acceptable amides, salts, esters and phospholipids.

75. The method of claims 74, wherein the composition contains less than 5% eicosapentaenoic, and their pharmaceutically acceptable amides, salts, esters and phospholipids.

76. The method of claims 74, wherein the composition contains less than 3% eicosapentaenoic, and their pharmaceutically acceptable amides, salts, esters and phospholipids.

77. The method of claims 74, wherein the composition contains less than 5% docosahexaenoic, and their pharmaceutically acceptable amides, salts, esters and phospholipids.

78. The method of claims 74, wherein the composition contains less than 3% docosahexaenoic, and their pharmaceutically acceptable amides, salts, esters and phospholipids.

79. The method of claim 50, wherein the composition contains ethyl icosapentate and/or ethyl docosahexaenoate.

80. The method of any of claims 58-64, wherein the total content of the emulsifier is 10 to 100 parts by weight in relation to 100 parts by weight of the at least one compound selected from the group consisting of omega-3 polyunsaturated fatty acids and their pharmaceutically acceptable amides, salts, esters and phospholipids.

81. The method of any of claims 58-64, wherein the total content of the emulsifier is 10 to 50 parts by weight in relation to 100 parts by weight of the at least one compound selected from the group consisting of EPA-E, EPA and its pharmaceutically acceptable amides, salts, esters and phospholipids.

82. The method of any of claims 1-20, wherein EPA-E, EPA or pharmaceutically acceptable amides, salts, esters or phospholipids thereof present in the composition is at least 40% by weight in total of the fatty acids and derivatives.

83. The method of any of claims 1-20, wherein the pharmaceutical composition is Epadel™, Lovaza™, Omacor ™, Lotriga™ or Vascepa ™.

84. The method of any of claims 1-9, wherein the subject's serum HbA1c level is equal to 6.4%.

85. The method of any of claims 1-9, wherein the subject's serum HbA1c level is between 5.7% and 6.4%.

86. The method of any of claims 1-9, wherein the subject's serum HbA1c level is 5.6%.

87. The method of any of claims 1-9, wherein the subject's serum HbA1c level less than 5.6%

88. The method of any of claims 1-9, wherein the subject's fasting glucose level is equal to 125 mg/dL.

89. The method of any of claims 1-9, wherein the subject's fasting glucose level is less than 125 mg/dL.

90. The method of any of claims 1-9, wherein the subject's fasting glucose level is between than 100 mg/dL and 125 mg/dL.

91. The method of any of claims 1-9, wherein the subject's fasting glucose level is equal to 100 mg/dL.

92. The method of any of claims 1-9, wherein the subject's fasting glucose level is less than 100 mg/dL.

93. The method of any of claims 1-9, wherein the subject's serum HbA1c level is measured using techniques selected from the following group: high-performance liquid chromatography (HPLC); immunoassay; enzymatic assay; colorimetric assay; capillary electrophoresis and boronate affinity chromatography.

94. The method of any of claims 1-9, wherein the subject's glucose level is measured using methods selected from the following: FPG, RPG and OGTT.

95. The method of any claims 10-15, wherein the subject shows a serum gamma glutamyl transferase (GGT) level equal to or less than 24 IU/L.

96. The method of any of claims 10-15, wherein the subject does not have a conditions selected from the following group consisting of alcoholic liver injury, drug-induced liver injury, chronic active hepatitis, cirrhosis, liver cancer, hepatic steatosis and biliary tract disease.

97. The method of any of claims 10-15, wherein the subject shows unobstructed or normal excretion of bile.

98. The method of any of claims 10-15, wherein the subject does not suffer from injury in the liver.

99. The method of any of claims 10-15, wherein the subject does not exhibit liver dysfunction.

100. The method of any of claims 10-15, wherein the subject shows normal levels of direct bilirubin.

101. The method of any of claims 10-15, wherein the subject shows does not possess biliary tract disease or the subject possesses biliary tract disease in an early stage.

102. The method of any of claims 10-15, wherein the selecting a subject having or suspected of having a fatty liver disease or disorder comprises selecting a subject with a normal serum direct bilirubin level equal to or less than 0.4.

103. The method of any of claims 16-20, wherein the NASH risk score is calculated using the formula: NASH Risk score = -6.4894 + 0.0078 x M30 (U/L) + 0.4668 x sFas (ng/mL).

104. The method of claims 16-20, wherein the subject does not have a conditions selected from the following group consisting of alcoholic liver injury, drug-induced liver injury, chronic active hepatitis, cirrhosis, liver cancer, hepatic steatosis and hepatocyte apoptosis.

105. The method of claims 16-20, wherein the subject does not suffer from injury in the liver.

106. The method of claims 16-20, wherein the subject does not exhibit liver dysfunction.

107. The method of claims 16-20, wherein the subject shows does not possess non or early stage hepatocyte apoptosis or the subject possess non or early stage hepatocyte apoptosis in an early stage.