What is claimed is:

1. A delayed release oral dosage form comprising:

(a) a non-porcine lipase; and

(b) an enteric material encompassing the non-porcine lipase.

2. The delayed release oral dosage form of claim 1, wherein the non-porcine lipase is a triacylglycerol hydrolase.

3. The delayed release oral dosage form of any of claims 1-2, wherein the non-porcine lipase has a molecular weight of about 30 kDa to about 45 kDa.

4. The delayed release oral dosage form of any of claims 1-3, wherein the non-porcine lipase has a molecular weight of about 37 kDa.

5. The delayed release oral dosage form of any of claims 1-4, wherein the non-porcine lipase contains from about 295 to about 310 amino acids.

6. The delayed release oral dosage form of any of claims 1-5, wherein the non-porcine lipase contains about 301 amino acids.

7. The delayed release oral dosage form of any of claims 1-6, wherein the non-porcine lipase is produced from *Yarrowia lipolytica*.

8. The delayed release oral dosage form of any of claims 1-7, wherein the non-porcine lipase is encoded by the Lip2 gene.

9. The delayed release oral dosage form of any of claims 1-8, wherein the non-porcine lipase is MS1819.

10. The delayed release oral dosage form of any of claims 1-9, comprising a capsule containing the non-porcine lipase, wherein the capsule comprises the enteric material, e.g., as a coating or dispersed within the capsule.

11. The delayed release oral dosage form of any of claims 1-9, comprising a tablet comprising the non-porcine lipase, wherein the tablet is overcoated with the enteric material.

12. The delayed release oral dosage form of any of claims 1-9, wherein the non-porcine lipase is combined with the enteric material in a solution and freeze dried or spray dried to form a powder.

13. The delayed release oral dosage form of any of claims 1-9 or 12, wherein the non-porcine lipase is in solution or suspension in a medium.

14. The delayed release oral dosage form of any of claims 1-9 or 12, wherein the powder is contained in a capsule, sachet or powder paper.

15. The delayed release oral dosage form of any preceding claim, wherein the enteric material comprises a naturally occurring material or a non-naturally occurring material.

16. The delayed release oral dosage form of any preceding claim, wherein the enteric material comprises a cellulosic material, an acrylic polymer, or a combination thereof.

17. The delayed release oral dosage form of any preceding claim, wherein the enteric material comprises hydroxypropylmethylcellulose acetate succinate.

18. The delayed release oral dosage form of any preceding claim, wherein the enteric material comprises methacrylic acid polymers, cellulose acetate phthalate polymers, hydroxypropylmethyl cellulose acetate succinate polymers, hydroxypropylmethyl cellulose phthalate polymers, polyvinyl acetate phthalate polymers or combinations thereof.

19. The delayed release oral dosage form of any preceding claim, wherein the enteric material comprises methyl acrylate-methacrylic acid copolymers, cellulose acetate succinate, hydroxy propyl methyl cellulose phthalate, hydroxy propyl methyl cellulose acetate succinate (hypromellose acetate succinate), polyvinyl acetate phthalate (PVAP), methyl methacrylate-methacrylic acid copolymers, shellac or combinations thereof.

20. The delayed release oral dosage form of any preceding claim, wherein the enteric material comprises hydroxypropyl methyl cellulose acetate succinate, hydroxypropyl methyl cellulose succinate, hydroxypropyl cellulose acetate succinate, hydroxyethyl methyl cellulose

succinate, hydroxyethyl cellulose acetate succinate, hydroxypropyl methyl cellulose phthalate, hydroxyethyl methyl cellulose acetate succinate, hydroxyethyl methyl cellulose acetate phthalate, carboxyethyl cellulose, carboxymethyl cellulose, cellulose acetate phthalate, methyl cellulose acetate phthalate, ethyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate, hydroxypropyl methyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate succinate, hydroxypropyl methyl cellulose acetate succinate phthalate, hydroxypropyl methyl cellulose succinate phthalate, cellulose propionate phthalate, hydroxypropyl cellulose butyrate phthalate, cellulose acetate trimellitate, methyl cellulose acetate trimellitate, ethyl cellulose acetate trimellitate, hydroxypropyl cellulose acetate trimellitate, hydroxypropyl methyl cellulose acetate trimellitate, hydroxypropyl cellulose acetate trimellitate succinate, cellulose propionate trimellitate, cellulose butyrate trimellitate, cellulose acetate terephthalate, cellulose acetate isophthalate, cellulose acetate pyridinedicarboxylate, salicylic acid cellulose acetate, hydroxypropyl salicylic acid cellulose acetate, ethylbenzoic acid cellulose acetate, hydroxypropyl ethylbenzoic acid cellulose acetate, ethyl phthalic acid cellulose acetate, ethyl nicotinic acid cellulose acetate, ethyl picolinic acid cellulose acetate or combinations thereof.

21. The delayed release oral dosage form of any preceding claim, wherein the enteric material is insoluble or substantially insoluble at a pH of less than about 4.

22. The delayed release oral dosage form of any preceding claim, wherein the enteric material does not crack, break or rupture at a pH of less than about 4.

23. The delayed release oral dosage form of any preceding claim, wherein the enteric material is soluble or substantially soluble at a pH of greater than about 5.

24. The delayed release oral dosage form of any preceding claim, wherein the enteric material cracks, breaks or ruptures at a pH of greater than about 5.

25. The delayed release oral dosage form of any preceding claim, wherein the dosage form releases less than about 10%, less than about 5%, less than about 3% or less than about 1% non-

porcine lipase at 30 minutes when tested in 900 mL simulated gastric fluid (buffer pH less than or equal to 3.0) at 37°C in a USP Apparatus II at 100 rpm with sinkers.

26. The delayed release oral dosage form of any preceding claim, wherein the dosage form releases less than about 10%, less than about 5%, less than about 3% or less than about 1% non-porcine lipase at 60 minutes when tested in 900 mL simulated gastric fluid (buffer pH less than or equal to 3.0) at 37°C in a USP Apparatus II at 100 rpm with sinkers.

27. The delayed release oral dosage form of any preceding claim, wherein the dosage form releases less than about 10%, less than about 5%, less than about 3% or less than about 1% non-porcine lipase at 90 minutes when tested in 900 mL simulated gastric fluid (buffer pH less than or equal to 3.0) at 37°C in a USP Apparatus II at 100 rpm with sinkers.

28. The delayed release oral dosage form of any preceding claim, wherein the dosage form releases less than about 10%, less than about 5%, less than about 3% or less than about 1% non-porcine lipase at 120 minutes when tested in 900 mL simulated gastric fluid (buffer pH less than or equal to 3.0) at 37°C in a USP Apparatus II at 100 rpm with sinkers.

29. The delayed release oral dosage form of any preceding claim, wherein the dosage form releases at least about 75%, at least about 90%, at least about 95% or at least about 99% non-porcine lipase at 15 minutes when tested in 900 mL simulated intestinal (buffer pH greater than or equal to 5.5) at 37°C in a USP Apparatus II at 100 rpm with sinkers.

30. The delayed release oral dosage form of any preceding claim, wherein the dosage form releases at least about 75%, at least about 90%, at least about 95% or at least about 99% non-porcine lipase at 30 minutes when tested in 900 mL simulated intestinal (buffer pH greater than or equal to 5.5) at 37°C in a USP Apparatus II at 100 rpm with sinkers.

31. The delayed release oral dosage form of any preceding claim, wherein the dosage form releases at least about 75%, at least about 90%, at least about 95% or at least about 99% non-

porcine lipase at 45 minutes when tested in 900 mL simulated intestinal (buffer pH greater than or equal to 5.5pH) at 37°C in a USP Apparatus II at 100 rpm with sinkers.

32. The delayed release oral dosage form of any preceding claim, wherein the dosage form releases at least about 75%, at least about 90%, at least about 95% or at least about 99% non-porcine lipase at 60 minutes when tested in 900 mL simulated intestinal (buffer pH greater than or equal to 5.5) at 37°C in a USP Apparatus II at 100 rpm with sinkers.

33. The delayed release oral dosage form of any preceding claim, that targets release of the non-porcine lipase in the duodenum of a patient in need thereof.

34. The delayed release oral dosage form of any preceding claim, wherein the non-porcine lipase is prepared by freeze drying.

35. The delayed release oral dosage form of any preceding claim, wherein the non-porcine lipase is prepared by spray drying.

36. The delayed release oral dosage form of claim 35, wherein the spray draying utilizes a stabilizer.

37. The delayed release oral dosage form of claim 36, wherein the stabilizer is an oligosaccharide.

38. The delayed release oral dosage form of claim 34 or 35, wherein the drying forms particles having a D50 of about 50 micron to about 150 micron, about 60 micron to about 120 micron, about 65 micron to about 85 micron or about 70 micron to about 82 micron.

39. The delayed release oral dosage form of claim 37, wherein the stabilizer is maltodextrin, xylan, mannan, fucoidan, galactomannan, chitosan, raffinose, stachyose, pectin, inulin, levan, graminan, and amylopectin, sucrose, lactulose, lactose, maltose, trehalose, cellobiose, nigerotriose, maltotriose, melezitose, maltotriulose, raffinose, kestose, or mixtures thereof.

40. The delayed release oral dosage form of any of claims 36-39, wherein the ratio of active to stabilizer is about 1:5 to about 5:1; about 1:3 to about 3:1; about 1:2 to about 2:1; about 1:1 or about 1:2.

41. The delayed release oral dosage form of any of claims 35-40, wherein the spray drying is performed at a pH of about 3 to about 5, about 2 to about 7 or about 6.

42. The delayed release oral dosage form of any of claims 35-41, wherein the spray drying is performed at a pH of about 4.

43. The delayed release oral dosage form of any of claims 35-42, wherein the spray drying is performed at a temperature of greater than about 125°C or from about 100°C to about 250°C or about 150°C to about 180°C or about 155°C to about 165°C or about 162°C.

44. The delayed release oral dosage form of any of claims 35-43, wherein the spray drying is performed at a temperature of greater than about 150°C.

45. The delayed release oral dosage form of any of claims 35-44, wherein the spray drying produces the non-porcine lipase at a yield of greater than about 80%, greater than about 90%, greater than about 95% or greater than about 99%.

46. The delayed release oral dosage form of any preceding claims, further comprising a second active agent.

47. The delayed release oral dosage form of claim 46, wherein the second active agent is a fat-soluble vitamin, a protease, an amylase, a porcine pancreatic enzyme replacement, other non-porcine replacements, or a combination thereof.

48. The delayed release oral dosage form of claim 47, wherein the fat-soluble vitamin is selected from vitamin A, D, E, K and combinations thereof.

49. The delayed release oral dosage form of claim 46, wherein the second active agent is pancrelipase, liprotamase or a combination thereof.

50. A method of treating exocrine pancreatic insufficiency comprising administering a delayed release dosage form according to any of claims 1-49.

51. A method of treating acute or chronic pancreatitis comprising administering a delayed release dosage form according to any of claims 1-49.

52. A method of treating cystic fibrosis comprising administering a delayed release dosage form according to any of claims 1-49.

53. The method of claim 40, wherein the insufficiency is caused by pancreatectomy such as due to pancreatic cancer.

54. The method of claim 50, wherein the insufficiency is age related or due to Schachman-Diamond Syndrome, diabetes type 1, diabetes type 2, HIV, celiac disease, or inflammatory bowel disease (such as ulcerative colitis or Crohn's disease).

55. The method of any of claims 50-54, wherein the dosage form is administered by feeding tube in the form of a solution or suspension or sparkled on food in the form of a powder.

56. The method of any of claims 50-55, that delivers at least a portion of the non-porcine lipase to the duodenum of the patient.

57. The method of claim 56, wherein the portion is at least about 75%.

58. The method of claim 56, wherein the portion is at least about 85%

59. The method of claim 56, wherein the portion is at least about 95%.

60. A process of preparing a delayed release oral dosage form comprising combining a non-porcine lipase and an enteric material to form a dosage form according to any of claims 1-49

61. A dosage form comprising:

(a) a non-porcine lipase; and

(b) a second active agent selected from a fat-soluble vitamin, a protease, an amylase, a porcine pancreatic enzyme replacement, other non-porcine replacements, or a combination thereof.

62. The dosage form of claim 61, wherein the fat-soluble vitamin is selected from vitamin A, D, E, K and combinations thereof.

63. The dosage form of claim 61, wherein the second active agent is pancrelipase, liprotamase or a combination thereof.

64. The dosage form of any of claims 61-63, wherein the non-porcine lipase and the second active agent are each independently immediate release, delayed release, sustained release or a combination thereof.

65. The dosage form of claim any of claims 61-64, wherein the non-porcine lipase is a triacylglycerol hydrolase.

66. The dosage form of any of claims 61-65, wherein the non-porcine lipase has a molecular weight of about 30 to about 45 kDa.

67. The dosage form of any of claims 61-66, wherein the non-porcine lipase has a molecular weight of about 37 kDa.

68. The dosage form of any of claims 61-67, wherein the non-porcine lipase contains from about 295 to about 310 amino acids.

69. The dosage form of any of claims 61-68, wherein the non-porcine lipase contains about 301 amino acids.

70. The dosage form of any of claims 61-69, wherein the non-porcine lipase is produced from *Yarrowia lipolytica*.

71. The dosage form of any of claims 61-70, wherein the non-porcine lipase is encoded by the Lip2 gene.

72. The dosage form of any of claims 61-71, wherein the non-porcine lipase is MS1819.

73. The dosage form of any of claims 61-72, comprising a capsule containing the combination.

74. The dosage form of any of claims 61-72, comprising a tablet comprising the combination.

75. The dosage form of any of claims 61-72, wherein combination is in solution or suspension in a medium.

76. The dosage form of any of claims 61-72, in the form of a powder.

77. The dosage form of claim 76, wherein the powder is contained in a capsule, sachet or powder paper.

78. The dosage form of any of claims 61-77, further comprising an enteric material that provides a delayed release of one or both of the active agents

79. The dosage form of claim 78, wherein the enteric material comprises a naturally occurring material or a non-naturally occurring material.

80. The dosage form of claim 78, wherein the enteric material comprises a cellulosic material, an acrylic polymer, or a combination thereof.

81. The dosage form of claim 78, wherein the enteric material comprises hydroxypropylmethylcellulose acetate succinate.

82. The dosage form of claim 78, wherein the enteric material comprises methacrylic acid polymers, cellulose acetate phthalate polymers, hydroxypropylmethyl cellulose acetate succinate polymers, hydroxypropylmethyl cellulose phthalate polymers, polyvinyl acetate phthalate polymers or combinations thereof.

83. The dosage form of claim 78, wherein the enteric material comprises methyl acrylate-methacrylic acid copolymers, cellulose acetate succinate, hydroxy propyl methyl cellulose phthalate, hydroxy propyl methyl cellulose acetate succinate (hypromellose acetate succinate), polyvinyl acetate phthalate (PVAP), methyl methacrylate-methacrylic acid copolymers, shellac or combinations thereof.

84. The dosage form of claim 78, wherein the enteric material comprises hydroxypropyl methyl cellulose acetate succinate, hydroxypropyl methyl cellulose succinate, hydroxypropyl cellulose acetate succinate, hydroxyethyl methyl cellulose succinate, hydroxyethyl cellulose acetate succinate, hydroxypropyl methyl cellulose phthalate, hydroxyethyl methyl cellulose acetate succinate, hydroxyethyl methyl cellulose acetate phthalate, carboxyethyl cellulose, carboxymethyl cellulose, cellulose acetate phthalate, methyl cellulose acetate phthalate, ethyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate, hydroxypropyl methyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate succinate, hydroxypropyl methyl cellulose acetate succinate phthalate, hydroxypropyl methyl cellulose succinate phthalate, cellulose propionate phthalate, hydroxypropyl cellulose butyrate phthalate, cellulose acetate trimellitate, methyl cellulose acetate trimellitate, ethyl cellulose acetate trimellitate, hydroxypropyl cellulose acetate trimellitate, hydroxypropyl methyl cellulose acetate trimellitate, hydroxypropyl cellulose acetate trimellitate succinate, cellulose propionate trimellitate, cellulose butyrate trimellitate, cellulose acetate terephthalate, cellulose acetate isophthalate, cellulose acetate pyridinedicarboxylate, salicylic acid cellulose acetate, hydroxypropyl salicylic acid cellulose acetate, ethylbenzoic acid cellulose acetate, hydroxypropyl ethylbenzoic acid cellulose acetate, ethyl phthalic acid cellulose acetate, ethyl nicotinic acid cellulose acetate, ethyl picolinic acid cellulose acetate or combinations thereof.

85. The dosage form of any of claims 78-84, wherein the enteric material is insoluble or substantially insoluble at a pH of less than about 4.

86. The dosage form of any of claims 78-84, wherein the enteric material is soluble or substantially soluble at a pH of greater than about 5.

87. The dosage form of any of claims 78-86, wherein the dosage form releases less than about 10%, less than about 5%, less than about 3% or less than about 1% of one or both of the

active agents at 30 minutes when tested in 900 mL simulated gastric fluid (buffer pH less than or equal to 3.0)) at 37°C in a USP Apparatus II at 100 rpm with or without sinkers.

88. The dosage form of any of claims 78-86, wherein the dosage form releases less than about 10%, less than about 5%, less than about 3% or less than about 1% of one or both of the active agents at 60 minutes when tested in 900 mL simulated gastric fluid (buffer pH less than or equal to 3.0) at 37°C in a USP Apparatus II at 100 rpm with or without sinkers.

89. The dosage form of any of claims 78-86, wherein the dosage form releases less than about 10%, less than about 5%, less than about 3% or less than about 1% of one or both of the active agents at 90 minutes when tested in 900 mL simulated gastric fluid (buffer pH less than or equal to 3.0)) at 37°C in a USP Apparatus II at 100 rpm with or without sinkers.

90. The dosage form of any of claims 78-86, wherein the dosage form releases less than about 10%, less than about 5%, less than about 3% or less than about 1% of one or both of the active agents at 120 minutes when tested in 900 mL simulated gastric fluid (buffer pH less than or equal to 3.0)) at 37°C in a USP Apparatus II at 100 rpm with or without sinkers.

91. The dosage form of any of claims 78-86, wherein the dosage form releases at least about 75%, at least about 90%, at least about 95% or at least about 99% of one or both of the active agents at 15 minutes when tested in 900 mL simulated intestinal (buffer pH 6.0) at 37°C in a USP Apparatus II at 100 rpm with sinkers.

92. The dosage form of any of claims 78-86, wherein the dosage form releases at least about 75%, at least about 90%, at least about 95% or at least about 99% of one or both of the active agents at 30 minutes when tested in 900 mL simulated intestinal (buffer pH greater than or equal to 5.5) at 37°C in a USP Apparatus II at 100 rpm with or without sinkers.

93. The dosage form of any of claims 78-86, wherein the dosage form releases at least about 75%, at least about 90%, at least about 95% or at least about 99% of one or both of the active

agents at 45 minutes when tested in 900 mL simulated intestinal (buffer pH greater than or equal to 5.5) at 37°C in a USP Apparatus II at 100 rpm with or without sinkers.

94. The dosage form of any of claims 78-86, wherein the dosage form releases at least about 75%, at least about 90%, at least about 95% or at least about 99% of one or both of the active agents at 60 minutes when tested in 900 mL simulated intestinal (buffer pH greater than or equal to 5.5) at 37°C in a USP Apparatus II at 100 rpm with or without sinkers.

95. The dosage form of any of claims 61-77, that provides an immediate release of one or both of the active agents.

96. The dosage form of claim 95, wherein the dosage form releases at least 75%, at least 85% or at least 95% one or both of the active agents at 30 minutes when tested in 900 mL simulated gastric fluid (buffer pH less than or equal to 3.0) at 37°C in a USP Apparatus II at 100 rpm with or without sinkers.

97. The dosage form of claim 95, wherein the dosage form releases at least 75%, at least 85% or at least 95% one or both of the active agents at 45 minutes when tested in 900 mL simulated gastric fluid (buffer pH less than or equal to 3.0) at 37°C in a USP Apparatus II at 100 rpm with or without sinkers.

98. The dosage form of claim 95, wherein the dosage form releases at least 75%, at least 85% or at least 95% one or both of the active agents at 60 minutes when tested in 900 mL simulated gastric fluid (buffer pH less than or equal to 3.0) at 37°C in a USP Apparatus II at 100 rpm with or without sinkers.

99. The dosage form of any of claims 61-98, wherein the non-porcine lipase is prepared by freeze drying.

100. The dosage form of any of claims 61-99, wherein the non-porcine lipase is prepared by spray drying.

101. The dosage form of claim 100, wherein the spray draying utilizes a stabilizer.

102. The dosage form of claim 101, wherein the stabilizer is an oligosaccharide.

103. The dosage form of claim 99 or 100, wherein the drying forms particles having a D50 of about 50 micron to about 150 micron, about 60 micron to about 120 micron, about 65 micron to about 85 micron or about 70 micron to about 82 micron.

104. The dosage form of claim 102, wherein the stabilizer is maltodextrin, xylan, mannan, fucoidan, galactomannan, chitosan, raffinose, stachyose, pectin, inulin, levan, graminan, and amylopectin, sucrose, lactulose, lactose, maltose, trehalose, cellobiose, nigerotriose, maltotriose, melezitose, maltotriulose, raffinose, kestose, or mixtures thereof.

105. The dosage form of any of claims 101-104, wherein the ratio of active to stabilizer is about 1:5 to about 5:1; about 1:3 to about 3:1; about 1:2 to about 2:1; about 1:1 or about 1:2.

106. The dosage form of any of claims 100-105, wherein the spray drying is performed at a pH of about 3 to about 5.

107. The dosage form of any of claims 100-106, wherein the spray drying is performed at a pH of about 4, about 2 to about 7 or about 6.

108. The dosage form of any of claims 100-107, wherein the spray drying is performed at a temperature of greater than about 125°C or from about 100°C to about 250°C or about 150°C to about 180°C or about 155°C to about 165°C or about 162°C.

109. The dosage form of any of claims 100-108, wherein the spray drying is performed at a temperature of greater than about 150°C.

110. The dosage form of any of claims 100-109, wherein the spray drying produces the non-porcine lipase at a yield of greater than about 80%, greater than about 90%, greater than about 95% or greater than about 99%.

111. A method of treating exocrine pancreatic insufficiency comprising administering a delayed release dosage form according to any of claims 1-110.

112. A method of treating acute or chronic pancreatitis comprising administering a delayed release dosage form according to any of claims 1-110.

113. A method of treating cystic fibrosis comprising administering a delayed release dosage form according to any of claims 1-110.

114. The method of claim 111, wherein the insufficiency is caused by pancreatectomy

115. The method of claim 111, wherein the insufficiency is age related or due to Schachman-Diamond Syndrome, diabetes type 1, diabetes type 2, HIV, celiac disease, or inflammatory bowel disease (such as ulcerative colitis or Crohn's disease).

116. The method of any of claims 111-115, wherein the dosage form is administered by feeding tube in the form of a solution or suspension or sparkled on food in the form of a powder.

117. The method of any of claims 111-116, that delivers at least a portion of the non-porcine lipase to the duodenum of the patient.

118. The method of claim 117, wherein the portion is at least about 75%.

119. The method of claim 117, wherein the portion is at least about 85%

120. The method of claim 117, wherein the portion is at least about 95%.

121. A process of preparing a dosage form comprising combining a non-porcine lipase and a second active agent to form a dosage form according to any of claims 61-110.

What is claimed is:

1. A delayed release oral dosage form comprising:

(a) a non-porcine lipase; and

(b) an enteric material encompassing the non-porcine lipase.

2. The delayed release oral dosage form of claim 1, wherein the non-porcine lipase is a triacylglycerol hydrolase.

3. The delayed release oral dosage form of any of claims 1-2, wherein the non-porcine lipase has a molecular weight of about 30 kDa to about 45 kDa, or wherein the non-porcine lipase has a molecular weight of about 37 kDa.

4. The delayed release oral dosage form of any of claims 1-3, wherein the non-porcine lipase contains from about 295 to about 310 amino acids, or wherein the non-porcine lipase contains about 301 amino acids.

5. The delayed release oral dosage form of any of claims 1-4, wherein the non-porcine lipase is produced from *Yarrowia lipolytica*, and/or is encoded by the Lip2 gene and/or is MS1819.

6. The delayed release oral dosage form of any of claims 1-5, comprising a capsule containing the non-porcine lipase, wherein the capsule comprises the enteric material, e.g., as a coating or dispersed within the capsule, or a tablet comprising the non-porcine lipase, wherein the tablet is overcoated with the enteric material.

7. The delayed release oral dosage form of any of claims 1-5, wherein the non-porcine lipase is combined with the enteric material in a solution and freeze dried or spray dried to form a powder.

8. The delayed release oral dosage form of any of claims 1-5 or 7, wherein the non-porcine lipase is in solution or suspension in a medium.

9. The delayed release oral dosage form of any of claims 1-5 or 7, wherein the powder is contained in a capsule, sachet or powder paper.

10. The delayed release oral dosage form of any preceding claim, wherein the enteric material comprises

a naturally occurring material or a non-naturally occurring material; and/or

a cellulosic material, an acrlic polymer, or a combination thereof; and/or

hydroxypropylmethylcellulose acetate succinate; and/or

methacrylic acid polymers, cellulose acetate phthalate polymers, hydroxypropylmethyl cellulose acetate succinate polymers, hydroxypropylmethyl cellulose phthalate polymers, polyvinyl acetate phthalate polymers or combinations thereof; and/or

methyl acrylate-methacrylic acid copolymers, cellulose acetate succinate, hydroxy propyl methyl cellulose phthalate, hydroxy propyl methyl cellulose acetate succinate (hypromellose acetate succinate), polyvinyl acetate phthalate (PVAP), methyl methacrylate-methacrylic acid copolymers, shellac or combinations thereof; and/or

hydroxypropyl methyl cellulose acetate succinate, hydroxypropyl methyl cellulose succinate, hydroxypropyl cellulose acetate succinate, hydroxyethyl methyl cellulose succinate, hydroxyethyl cellulose acetate succinate, hydroxypropyl methyl cellulose phthalate, hydroxyethyl methyl cellulose acetate succinate, hydroxyethyl methyl cellulose acetate phthalate, carboxyethyl cellulose, carboxymethyl cellulose, cellulose acetate phthalate, methyl cellulose acetate phthalate, ethyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate, hydroxypropyl methyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate succinate, hydroxypropyl methyl cellulose acetate succinate phthalate, hydroxypropyl methyl cellulose succinate phthalate, cellulose propionate phthalate, hydroxypropyl cellulose butyrate phthalate, cellulose acetate trimellitate, methyl cellulose acetate trimellitate, ethyl cellulose acetate trimellitate, hydroxypropyl cellulose acetate trimellitate, hydroxypropyl

methyl cellulose acetate trimellitate, hydroxypropyl cellulose acetate trimellitate succinate, cellulose propionate trimellitate, cellulose butyrate trimellitate, cellulose acetate terephthalate, cellulose acetate isophthalate, cellulose acetate pyridinedicarboxylate, salicylic acid cellulose acetate, hydroxypropyl salicylic acid cellulose acetate, ethylbenzoic acid cellulose acetate, hydroxypropyl ethylbenzoic acid cellulose acetate, ethyl phthalic acid cellulose acetate, ethyl nicotinic acid cellulose acetate, ethyl picolinic acid cellulose acetate or combinations thereof.

11. The delayed release oral dosage form of any preceding claim, wherein the enteric material is insoluble or substantially insoluble at a pH of less than about 4.

12. The delayed release oral dosage form of any preceding claim, wherein the enteric material does not crack, break or rupture at a pH of less than about 4.

13. The delayed release oral dosage form of any preceding claim, wherein the enteric material is soluble or substantially soluble at a pH of greater than about 5.

14. The delayed release oral dosage form of any preceding claim, wherein the enteric material cracks, breaks or ruptures at a pH of greater than about 5.

15. The delayed release oral dosage form of any preceding claim, wherein the dosage form releases less than about 10%, less than about 5%, less than about 3% or less than about 1% non-porcine lipase at 30 minutes when tested in 900 mL simulated gastric fluid (buffer pH less than or equal to 3.0) at 37°C in a USP Apparatus II at 100 rpm with sinkers;

or

wherein the dosage form releases less than about 10%, less than about 5%, less than about 3% or less than about 1% non-porcine lipase at 60 minutes when tested in 900 mL simulated gastric fluid (buffer pH less than or equal to 3.0) at 37°C in a USP Apparatus II at 100 rpm with sinkers;

or

wherein the dosage form releases less than about 10%, less than about 5%, less than about 3% or less than about 1% non-porcine lipase at 90 minutes when tested in 900 mL simulated gastric

fluid (buffer pH less than or equal to 3.0) at 37°C in a USP Apparatus II at 100 rpm with sinkers;

or

The delayed release oral dosage form of any preceding claim, wherein the dosage form releases less than about 10%, less than about 5%, less than about 3% or less than about 1% non-porcine lipase at 120 minutes when tested in 900 mL simulated gastric fluid (buffer pH less than or equal to 3.0) at 37°C in a USP Apparatus II at 100 rpm with sinkers.

16. The delayed release oral dosage form of any preceding claim, wherein the dosage form releases at least about 75%, at least about 90%, at least about 95% or at least about 99% non-porcine lipase at 15 minutes when tested in 900 mL simulated intestinal (buffer pH greater than or equal to 5.5) at 37°C in a USP Apparatus II at 100 rpm with sinkers;

or

wherein the dosage form releases at least about 75%, at least about 90%, at least about 95% or at least about 99% non-porcine lipase at 30 minutes when tested in 900 mL simulated intestinal (buffer pH greater than or equal to 5.5) at 37°C in a USP Apparatus II at 100 rpm with sinkers;

or

wherein the dosage form releases at least about 75%, at least about 90%, at least about 95% or at least about 99% non-porcine lipase at 45 minutes when tested in 900 mL simulated intestinal (buffer pH greater than or equal to 5.5pH) at 37°C in a USP Apparatus II at 100 rpm with sinkers; or

wherein the dosage form releases at least about 75%, at least about 90%, at least about 95% or at least about 99% non-porcine lipase at 60 minutes when tested in 900 mL simulated intestinal (buffer pH greater than or equal to 5.5) at 37°C in a USP Apparatus II at 100 rpm with sinkers.

17. The delayed release oral dosage form of any preceding claim, that targets release of the non-porcine lipase in the duodenum of a patient in need thereof.

18. The delayed release oral dosage form of any preceding claim, wherein the non-porcine lipase is prepared by freeze drying.

19. The delayed release oral dosage form of any preceding claim, wherein the non-porcine lipase is prepared by spray drying, utilizing a stabilizer, wherein the stabilizer is an oligosaccharide.

20. The delayed release oral dosage form of claim 18 or 19, wherein the drying forms particles having a D50 of about 50 micron to about 150 micron, about 60 micron to about 120 micron, about 65 micron to about 85 micron or about 70 micron to about 82 micron.

21. The delayed release oral dosage form of claim 19, wherein the stabilizer is maltodextrin, xylan, mannan, fucoidan, galactomannan, chitosan, raffinose, stachyose, pectin, inulin, levan, graminan, and amylopectin, sucrose, lactulose, lactose, maltose, trehalose, cellobiose, nigerotriose, maltotriose, melezitose, maltotriulose, raffinose, kestose, or mixtures thereof.

22. The delayed release oral dosage form of any of claims 20-21, wherein the ratio of active to stabilizer is about 1:5 to about 5:1; about 1:3 to about 3:1; about 1:2 to about 2:1; about 1:1 or about 1:2.

23. The delayed release oral dosage form of any of claims 19-22, wherein the spray drying is performed at a pH of about 3 to about 5, about 2 to about 7, about 6, or about 4.

24. The delayed release oral dosage form of any of claims 19-23, wherein the spray drying is performed at a temperature of greater than about 125°C or from about 100°C to about 250°C or about 150°C to about 180°C or about 155°C to about 165°C or about 162°C.

25. The delayed release oral dosage form of any of claims 19-24, wherein the spray drying is performed at a temperature of greater than about 150°C.

26. The delayed release oral dosage form of any of claims 19-25, wherein the spray drying produces the non-porcine lipase at a yield of greater than about 80%, greater than about 90%, greater than about 95% or greater than about 99%.

27. The delayed release oral dosage form of any preceding claims, further comprising a second active agent.

28. The delayed release oral dosage form of claim 46, wherein the second active agent is a fat-soluble vitamin, a protease, an amylase, a porcine pancreatic enzyme replacement, other non-porcine replacements, or a combination thereof.

29. A method of treating exocrine pancreatic insufficiency comprising administering a delayed release dosage form according to any of claims 1-28.

30. A method of treating acute or chronic pancreatitis comprising administering a delayed release dosage form according to any of claims 1-28.

31. A method of treating cystic fibrosis comprising administering a delayed release dosage form according to any of claims 1-28.

32. A process of preparing a delayed release oral dosage form comprising combining a non-porcine lipase and an enteric material to form a dosage form according to any of claims 1-28.