UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

RONNIE GLASPER Plaintiff, vs. FRESENIUS MEDICAL CARE HOLDING, INC., FRESENIUS MEDICAL CARE HOLDING, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA, FRESENIUS USA, INC., FRESENIUS USA MANUFACTURING, INC., FRESENIUS USA MARKETING, INC., FRESENIUS MEDICAL CARE AG & CO. KGAA, FRESENIUS MEDICAL CARE MANAGEMENT, AG, FRESENIUS SE & CO. KGAA, and FRESENIUS MANAGEMENT, SE. Defendants.	CIVIL ACTION NO. COMPLAINT JURY TRIAL DEMANDED SECTION MAGISTRATE

COMPLAINT

NOW INTO COURT, come Plaintiff, RONNIE GLASPER who, by and through counsel, brings this action against the Defendants, FRESENIUS MEDICAL CARE HOLDING, INC., FRESENIUS MEDICAL CARE HOLDING, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA, FRESENIUS USA, INC., FRESENIUS USA MANUFACTURING, INC., FRESENIUS USA MARKETING, INC., FRESENIUS MEDICAL CARE AG & CO. KGAA, FRESENIUS MEDICAL CARE MANAGEMENT, AG, FRESENIUS SE & CO. KGAA, and FRESENIUS MANAGEMENT, SE and allege the following upon information, belief and investigation of counsel:

NATURE OF THE CASE

1. This is a product liability action brought by Plaintiff , who suffered damages as a result of his receipt of NATURALYTE LIQUID ACID CONCENTRATE (hereinafter

"NATURALYTE") and/or GRANUFLO DRY ACID CONCENTRATE (hereinafter "GRANUFLO") during dialysis.

2. Defendants, FRESENIUS MEDICAL CARE HOLDING, INC., FRESENIUS MEDICAL CARE HOLDING, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA, FRESENIUS USA, INC., FRESENIUS USA MANUFACTURING, INC., FRESENIUS USA MARKETING, INC., FRESENIUS MEDICAL CARE AG & CO. KGAA, FRESENIUS MEDICAL CARE MANAGEMENT, AG, FRESENIUS SE & CO. KGAA, and FRESENIUS MANAGEMENT, SE (hereinafter referred to as "Fresenius," "Fresenius Defendants" and/or "Defendants"), designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed NATURALYTE and/or GRANUFLO for use as acid concentrates during hemodialysis.

3. When warning of the safety, risks and/or defects of NATURALYTE and/or GRANUFLO, Defendants concealed their knowledge of NATURALYTE's and/or GRANUFLO's safety, risks and/or defects from Plaintiff, the FDA, the public in general and/or the medical community, specifically that NATURALYTE and/or GRANUFLO could cause serious and grave health consequences, including but not limited to death, cardiopulmonary arrest, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, heart attack, stroke and/or hypotension.

4. Defendants negligently and/or fraudulently represented to the medical and healthcare community, the Food and Drug Administration (hereinafter referred to as "FDA"), the Plaintiff and the public in general that NATURALYTE and/or GRANUFLO had been tested and were found to be safe and/or effective for their indicated use – as acid concentrates to be administered during hemodialysis.

5. When warning of the safety, risks and/or defects of NATURALYTE and/or GRANUFLO, Defendants negligently and/or fraudulently represented to the medical and healthcare community, the FDA, the Plaintiff and the public in general that NATURALYTE and/or GRANUFLO had been tested and were found to be safe and/or effective for their indicated use – as acid concentrates to be administered during hemodialysis.

6. These representations and concealments were made by Defendants with the intent of defrauding and/or deceiving the Plaintiff, the public in general and the medical and healthcare community, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense, prescribe, administer and/or otherwise use NATURALYTE and/or GRANUFLO as acid concentrates during hemodialysis, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff herein.

7. Defendants negligently and improperly failed to perform sufficient tests, if any, concerning NATURALYTE 's and/or GRANUFLO's potential to cause serious and grave health consequences, including but not limited to death, cardiopulmonary arrest, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, heart attack, stroke and/or hypotension, during clinical trials.

8. As a result of the defective nature of Defendants' NATURALYTE and/or GRANUFLO, Plaintiff has suffered, is suffering and/or will suffer severe and permanent personal injuries.

9. As a result of Defendants' failure to warn about the defective nature of Defendants' NATURALYTE and/or GRANUFLO, Plaintiff has suffered, is suffering and/or will suffer severe and permanent personal injuries.

10. Plaintiff seeks damages as a result of Defendants' NATURALYTE and/or GRANUFLO which was prescribed, was administered, received and/or otherwise used by Plaintiff and caused him to suffer severe and permanent personal injuries and mental anguish as well as caused him to incur medical expenses and other economic losses.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction). The amount in controversy exceeds $75,000.00 exclusive of interest and costs. There is complete diversity of citizenship between the Plaintiff and Defendants. Plaintiff is a resident of the State of Louisiana. All Defendants are corporations of states other than the State of Louisiana, and all Defendants have their principal place of business in a state other than the State of Louisiana.

12. This Court has personal jurisdiction over the Defendants, each of which is licensed to conduct and/or is systematically and continuously conducting business in this State, including, but not limited to, the marketing, advertising, selling, and distributing drugs, including NATURALYTE and/or GRANUFLO, to residents in this State.

13. Venue is proper in this District pursuant to 28 U.D.C. § 1391(a) because the Defendants marketed, advertised, and distributed the dangerous product in this Federal District, and caused harm to the Plaintiff who resides within this District. The Plaintiff resides in this Federal District and the damages occurred in this Federal District. The Defendants do substantial business in the State of Louisiana and within this Federal District, and at all times

relevant hereto, the Defendants developed, manufactured, promoted, marketed, distributed, tested, warranted, and sold NATURALYTE and/or GRANUFLO in interstate commerce.

PARTIES

14. Plaintiff RONNIE GLASPER was at all relevant times, an adult resident of the State of Louisiana. He was prescribed NATURALYTE and/or GRANUFLO and did ingest NATURALYTE and/or GRANUFLO. Plaintiff has suffered damages as a result of Defendants' illegal and wrongful conduct described below.

15. Upon information and belief, Plaintiff RONNIE GLASPER was administered and/or received NATURALYTE and/or GRANUFLO while receiving dialysis treatments at Fresenius Medical Care in Ferriday, Louisiana.

16. Upon information and belief, as a direct and proximate result of the use of Defendants' NATURALYTE and/or GRANUFLO, Plaintiff RONNIE GLASPER suffered a heart attack and stroke as well as severe pain and suffering.

17. Defendant FRESENIUS MEDICAL CARE HOLDING, INC. is a New York Corporation, which has its principle place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

18. At all times relevant herein, FRESENIUS MEDICAL CARE HOLDING, INC. was engaged in the business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling the prescription drug NATURALYTE and/or GRANUFLO to the general public, including Plaintiff.

19. At all times relevant herein, Defendant FRESENIUS MEDICAL CARE HOLDING, INC. was authorized to do business within the State of Louisiana; did in fact transact and conduct business in the State of Louisiana; and derived substantial revenue from goods and products used in the State of Louisiana.

20. Defendant FRESENIUS MEDICAL CARE HOLDING, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA is a New York Corporation, which has its principle place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

21. At all times relevant herein, FRESENIUS MEDICAL CARE HOLDING, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA was engaged in the business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling the prescription drug NATURALYTE and/or GRANUFLO to the general public, including Plaintiff.

22. At all times relevant herein, Defendant FRESENIUS MEDICAL CARE HOLDING, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA was authorized to do business within the State of Louisiana; did in fact transact and conduct business in the State of Louisiana; and derived substantial revenue from goods and products used in the State of Louisiana.

23. Defendant FRESENIUS USA, INC. is a Delaware Corporation, which has its principle place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

24. At all times relevant herein, FRESENIUS USA, INC. was engaged in the business of, or was successor in interest to, entities engaged in the business of researching, licensing,

designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling the prescription drug NATURALYTE and/or GRANUFLO to the general public, including Plaintiff.

25. At all times relevant herein, Defendant FRESENIUS USA, INC. was authorized to do business within the State of Louisiana; did in fact transact and conduct business in the State of Louisiana; and derived substantial revenue from goods and products used in the State of Louisiana.

26. Defendant FRESENIUS USA MANUFACTURING, INC. is a Delaware Corporation, which has its principle place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

27. At all times relevant herein, FRESENIUS USA MANUFACTURING, INC. was engaged in the business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling the prescription drug NATURALYTE and/or GRANUFLO to the general public, including Plaintiff.

28. At all times relevant herein, Defendant FRESENIUS USA MANUFACTURING, INC. was authorized to do business within the State of Louisiana; did in fact transact and conduct business in the State of Louisiana; and derived substantial revenue from goods and products used in the State of Louisiana.

29. Defendant FRESENIUS USA MARKETING, INC. is a Delaware Corporation, which has its principle place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

30. At all times relevant herein, FRESENIUS USA MARKETING, INC. was engaged in the business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling the prescription drug NATURALYTE and/or GRANUFLO to the general public, including Plaintiff.

31. At all times relevant herein, Defendant FRESENIUS USA MARKETING, INC. was authorized to do business within the State of Louisiana; did in fact transact and conduct business in the State of Louisiana; and derived substantial revenue from goods and products used in the State of Louisiana.

32. Upon information and belief, Defendants FRESENIUS USA, INC., FRESENIUS USA MANUFACTURING, INC., FRESENIUS USA MARKETING, INC. are wholly owned subsidiaries of Defendants FRESENIUS MEDICAL CARE HOLDING, INC. and/or FRESENIUS MEDICAL CARE HOLDING, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA.

33. Defendant FRESENIUS MEDICAL CARE AG & CO. KGAA is a partnership limited by shares organized under the laws of Germany having its headquarters and principal place of business at 61352 Bad Homburg, Germany with a postal address of 61346 Bad Homburg, Germany.

34. Defendant FRESENIUS MEDICAL CARE AG & CO. KGAA, a partnership limited by shares, was formerly known as FRESENIUS MEDICAL CARE AG, a stock corporation. FRESENIUS MEDICAL CARE AG & CO. KGAA is the same legal business entity as FRESENIUS MEDICAL CARE AG.

35. Defendant FRESENIUS MEDICAL CARE AG & CO. KGAA is and was at all relevant times the parent company of Defendants FRESENIUS MEDICAL CARE HOLDING, INC. and/or FRESENIUS MEDICAL CARE HOLDING, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA.

36. Defendant FRESENIUS MEDICAL CARE AG & CO. KGAA at all times relevant herein was in business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling the prescription drug NATURALYTE and/or GRANUFLO to the general public, including Plaintiff.

37. At all times relevant herein, Defendant FRESENIUS MEDICAL CARE AG & CO. KGAA was authorized to do business within the State of Louisiana; did in fact transact and conduct business in the State of Louisiana; and derived substantial revenue from goods and products used in the State of Louisiana.

38. Defendant FRESENIUS MEDICAL CARE MANAGEMENT, AG is a corporation organized under the laws of Germany having its headquarters and principal place of business at 61352 Bad Homburg, Germany with a postal address of 61346 Bad Homburg, Germany.

39. Defendant FRESENIUS MEDICAL CARE MANAGEMENT, AG is the general partner of Defendant FRESENIUS MEDICAL CARE AG & CO. KGAA, and is responsible for the management of Defendant FRESENIUS MEDICAL CARE AG & CO. KGAA.

40. Defendant FRESENIUS MEDICAL CARE MANAGEMENT, AG was the majority voting shareholder of FRESENIUS MEDICAL CARE AG & CO. KGAA, when it was

known as FRESENIUS MEDICAL CARE AG and was responsible for the management of Defendant FRESENIUS MEDICAL CARE AG & CO. KGAA, when it was known as FRESENIUS MEDICAL CARE AG.

41. Defendant FRESENIUS MEDICAL CARE MANAGEMENT, AG at all times relevant herein was in business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling the prescription drug NATURALYTE and/or GRANUFLO to the general public, including Plaintiff.

42. At all times relevant herein, Defendant FRESENIUS MEDICAL CARE MANAGEMENT, AG was authorized to do business within the State of Louisiana; did in fact transact and conduct business in the State of Louisiana; and derived substantial revenue from goods and products used in the State of Louisiana.

43. Defendant FRESENIUS MEDICAL CARE MANAGEMENT, AG is and was at all times relevant herein a wholly owned subsidiary of the Defendant FRESENIUS SE & CO. KGAA.

44. Defendant FRESENIUS SE & CO. KGAA is a partnership limited by shares organized under the laws of Germany having its headquarters and principal place of business at 61352 Bad Homburg, Germany with a postal address of 61346 Bad Homburg, Germany.

45. Defendant FRESENIUS SE & CO. KGAA was formerly known as FRESENIUS SE, which was formerly known as FRESENIUS AG. FRESENIUS SE & CO. KGAA is the same legal entity as FRESENIUS SE and FRESENIUS AG.

46. Defendant FRESENIUS SE & CO. KGAA at all times relevant herein was in business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling the prescription drug NATURALYTE and/or GRANUFLO to the general public, including Plaintiff.

47. At all times relevant herein, Defendant FRESENIUS SE & CO. KGAA was authorized to do business within the State of Louisiana; did in fact transact and conduct business in the State of Louisiana; and derived substantial revenue from goods and products used in the State of Louisiana.

48. Defendant FRESENIUS MANAGEMENT, SE is a corporation organized under the laws of Germany having its headquarters and principal place of business at 61352 Bad Homburg, Germany with a postal address of 61346 Bad Homburg, Germany.

49. Defendant FRESENIUS MANAGEMENT, SE is the general partner of FRESENIUS SE & CO. KGAA and is responsible for the management of Defendant FRESENIUS SE & CO. KGAA.

50. Defendant FRESENIUS MANAGEMENT, SE was the majority voting shareholder of FRESENIUS SE & CO. KGAA, when it was known as FRESENIUS SE, and was responsible for the management of Defendant FRESENIUS SE & CO. KGAA, when it was known as Defendant FRESENIUS SE.

51. Defendant FRESENIUS MANAGEMENT, SE was the majority voting shareholder of FRESENIUS SE & CO. KGAA, when it was known as FRESENIUS AG, and

was responsible for the management of Defendant FRESENIUS SE & CO. KGAA, when it was known as Defendant FRESENIUS AG.

52. Defendant FRESENIUS MANAGEMENT, SE at all times relevant herein was in business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling the prescription drug NATURALYTE and/or GRANUFLO to the general public, including Plaintiff.

53. At all times relevant herein, Defendant FRESENIUS MANAGEMENT, SE was authorized to do business within the State of Louisiana; did in fact transact and conduct business in the State of Louisiana; and derived substantial revenue from goods and products used in the State of Louisiana.

FACTUAL BACKGROUND

A. Hemodialysis in General

54. Hemodialysis is a method of treating acute and chronic kidney disease, especially where conservative treatment has been judged inadequate.

55. Hemodialysis is a treatment that attempts to replace the function of a normal kidney by filtering waste and removing extra fluids and electrolytes from the body.

56. A person undergoing hemodialysis is connected to a hemodialysis machine and then blood is removed from the body. A dialysate is utilized in the hemodialysis machine to remove the waste from the blood. Once the waste is removed, the blood is returned to the body.

57. Many patients who suffer from kidney disease also suffer from a condition known as metabolic acidosis (too much acid in the body) because the kidneys are failing to remove excess acid from the body.

58. One goal of hemodialysis is to attempt to bring the body's acid levels into balance. This can be done through the use of a base - a bicarbonate dialysate - where the bicarbonate acts as a pH buffer to neutralize the metabolic acidosis.

59. Because kidney failure also affects the body's ability to produce electrolytes, such as calcium and magnesium, these same electrolytes are introduced into the blood during hemodialysis. However, because the bicarbonates when combined with calcium and/or magnesium react to create an insoluble substance, an acid concentrate is added to the bicarbonate dialysate to prevent this from occurring.

60. Defendants' NATURALYTE and GRANUFLO are acid concentrates.

61. When introduced into the body, the acid contained within acid concentrates is converted into bicarbonates by the liver, which increases bicarbonate levels in the blood.

62. As a result, a person undergoing hemodialysis receives bicarbonates from two sources: (1) the bicarbonate solution introduced during dialysis; and (2) the acid concentrate when it reaches the liver.

63. If an individual undergoing dialysis is administered and/or receives an excess of bicarbonates from one and/or both sources, metabolic alkalosis can occur.

64. Metabolic alkalosis is a medical condition in which there is too much bicarbonate or base in the blood. It is the converse of metabolic acidosis.

65. Metabolic alkalosis is a medical condition which, if left undiagnosed and/or untreated, can lead to serious adverse events, including but not limited to electrolyte imbalances,

hypokalemia, hypercapnia, hypotension, hypoxemia, heart arrhythmias, heart attacks, coma, cardiac arrest, stroke and/or death.

66. Given that a person undergoing hemodialysis receives bicarbonates from two sources (the bicarbonate solution and the acid concentrate), a prescribing physician and/or healthcare facility must ensure that the individual undergoing dialysis is receiving enough bicarbonates, from both sources, to address the individual's acid levels in the blood, but not excessive amounts of bicarbonates so as to cause metabolic alkalosis.

67. As such, it is imperative that the manufacturer of a product used in hemodialysis, such as an acid concentrate, advise and/or warn prescribing physicians and/or healthcare facilities of any and all risks, concerns, defects and other safety information regarding said product.

B. NATURALYTE and GRANUFLO – The Recall

68. NATURALYTE and/or GRANUFLO are acid concentrates designed, manufactured, marketed, advertised, distributed, and sold by Defendants to be used with a bicarbonate concentrate to create a bicarbonate dialysate for hemodialysis.

69. NATURALYTE contains 4.0 mEq/L of acetate.

70. GRANUFLO contains 8.0 mEq/L of acetate.

71. NATURALYTE and/or GRANUFLO are regulated as medical devices by the United States Food and Drug Administration ("FDA").

72. NATURALYTE and/or GRANUFLO are registered trademarks of the Defendants.

73. NATURALYTE and/or GRANUFLO were submitted for approval by the FDA through the 510(k) process as opposed to the FDA's more rigorous premarket approval process.

74. Upon information and belief, Defendants submitted their NATURALYTE and/or GRANUFLO acid concentrates for approval pursuant to the 510(k) approval process as opposed to the FDA's more rigorous premarket approval process so that they could bypass the premarket approval process, which would have obligated them to design and implement a clinical investigation regarding the products and to submit the results of that investigation to the FDA for review.

75. Upon information and belief, on or about April 23, 1981, Defendants' NATURALYTE 9000 Series was approved for marketing, sale and use pursuant to the 510(k) approval process.

76. Upon information and belief, on or about December 3, 1982 Defendants' NATURALYTE 4000 Series was approved for marketing, sale and use pursuant to the 510(k) approval process.

77. Upon information and belief, on or about July 26, 1985 Defendants NATURALYTE 6000 Series was approved for marketing, sale and use pursuant to the 510(k) approval process.

78. Upon information and belief, on or about January 18, 2007 Defendants submitted a premarket notification of their intent to market their previously approved NATURALYTE acid concentrates with a modified formula ("NATURALYTE January 510(k) submission") in the United States to the FDA.

79. Upon information and belief, Defendants' NATURALYTE's January 510(k) submission to the FDA included Defendants' unilateral finding that NATURALYTE was substantially equivalent to its previously approved NATURALYTE acid concentrates.

80. Upon information and belief, based upon information provided to them by Defendants, the FDA approved NATURALYTE with its modified formula for marketing, sale and use on or about March 29, 2007.

81. Upon information and belief, on or about April 29, 1992 Defendants submitted a premarket notification of their intent to market GRANUFLO in a granulated formula ("GRANUFLO April 510(k) submission") in the United States to the FDA.

82. Upon information and belief, Defendants' GRANUFLO April 510(k) submission to the FDA included Defendants' unilateral finding that GRANUFLO in a granulated formula was substantially equivalent to other products on the market.

83. Upon information and belief, Defendants' GRANUFLO that was the subject of their GRANUFLO April 510(k) submission to the FDA did not contain diacetate.

84. Upon information and belief, based upon information provided to them by Defendants, the FDA originally approved GRANUFLO in a granulated formula for marketing, sale and use on or about March 30, 1994.

85. Upon information and belief, in or about August 2002, Defendants altered the formula of their GRANUFLO by switching from the acid used in said product to diacetate.

86. Upon information and belief, Defendants' goal in using diacetate in their GRANUFLO was to counter the negative effects of metabolic acidosis by increasing bicarbonate levels in the blood via an acid concentrate as opposed to and/or in addition to a bicarbonate solution.

87. Upon information and belief, Defendants' goal in using diacetate in their GRANUFLO was to improve pre-dialysis bicarbonate levels in the blood.

88. In or about August 2002, Defendants began administering their GRANUFLO with diacetate to dialysis patients.

89. Upon information and belief, in or about August 2002, Defendants began administering their GRANUFLO with diacetate to dialysis patients without FDA approval.

90. On or about January 14, 2003 Defendants submitted a premarket notification of their intent to market GRANUFLO in a non-granulated formula in the United States to the FDA ("GRANUFLO January 510(k) submission").

91. Defendants' GRANUFLO that was subject to the January 510(k) submission contained diacetate.

92. Within their GRANUFLO January 510(k) submission, Defendants did not advise the FDA and/or concealed from the FDA that they had begun administering their GRANUFLO with diacetate to dialysis patients in or about August 2002.

93. Defendants' GRANUFLO January 510(k) submission to the FDA included Defendants' unilateral finding that GRANUFLO in a non-granulated formula was substantially equivalent to other products on the market, including their GRANUFLO that was approved by the FDA on or about March 30, 1994.

94. Within Defendants' GRANUFLO's January 510(k) submission to the FDA, Defendants represented to the FDA that their GRANUFLO in a non-granulated formula would be used as a direct product replacement for their previously approved GRANUFLO.

95. Within Defendants' GRANUFLO's January 510(k) submission to the FDA, Defendants represented to the FDA that their GRANUFLO in a non-granulated formula had the same chemical composition as their previously approved GRANUFLO.

96. Within Defendants' GRANUFLO's January 510(k) submission to the FDA, Defendants failed to notify and/or inform the FDA that their GRANUFLO in a non-granulated formula contained diacetate.

97. Within Defendants' GRANUFLO's January 510(k) submission to the FDA, Defendants intentionally, willfully, recklessly and/or negligently hid, omitted and concealed from the FDA that their GRANUFLO in a non-granulated formula contained diacetate.

98. Upon information and belief, Defendants intentionally drafted their January 510(k) submission in such a manner so as to mislead the FDA into believing that their GRANUFLO in a non-granulated formula contained the same type of acid as their previously approved GRANUFLO so as to support a finding by the FDA that the products were substantially similar.

99. Upon information and belief, based upon information provided to them by Defendants, the FDA originally approved GRANUFLO in a non-granulated formula for marketing, sale and use on or about May 20, 2003.

100. Upon information and belief, following its approval by the FDA, Defendants only manufactured, marketed, promoted, advertised, marketed, distributed and/or sold GRANUFLO containing dialysate.

101. Upon information and belief, following its approval by the FDA, Defendants only manufactured, marketed, promoted, advertised, marketed, distributed and/or sold GRANUFLO containing 8.0 mEq/L, which is equivalent to 4.0 mEq/L more acetate than any other acid concentrate on the market.

102. Upon information and belief, following its approval by the FDA, the Defendants never communicated to all treating physicians and/or healthcare facilities administering and/or using GRANUFLO that bicarbonate levels needed to be adjusted to take into account the additional acetate provided by GRANUFLO.

103. In or about 2004, Defendants conducted a retrospective study of dialysis patients who had converted from previously approved acid concentrates to GRANUFLO containing diacetate between August 2002 and April 2003 ("Defendants' 2004 Retrospective Study).

104. Upon information and belief, the goal of Defendants' 2004 Retrospective Study was to determine the efficacy of acid concentrate containing diacetate (i.e. GRANUFLO) in resolving and/or reducing metabolic acidosis when compared with a standard acid concentrate.

105. Upon information and belief, the goal of Defendants' 2004 Retrospective Study was to determine the efficacy of acid concentrate containing diacetate (i.e. GRANUFLO) in improving pre-dialysis bicarbonate levels in the blood.

106. In or about 2004, Defendants evaluated the results of their 2004 Retrospective Study which revealed, among other things, higher than normal post-dialysis bicarbonate levels as a result of the administration of GRANUFLO containing diacetate.

107. In or about 2004, Defendants evaluated the results of their 2004 Retrospective Study which revealed, among other things, higher than normal pre-dialysis bicarbonate levels as a result of the administration of GRANUFLO containing diacetate.

108. In or about 2004, Defendants evaluated the results of their 2004 Retrospective Study which revealed, among other things, an increase in cases of metabolic alkalosis as a result of the administration of GRANUFLO containing diacetate.

109. In or about 2004, Defendants evaluated the results of their 2004 Retrospective Study which revealed, among other things, a significant increase in cases of metabolic alkalosis as a result of the administration of GRANUFLO containing diacetate.

110. As a result of their 2004 Retrospective Study Defendants were on notice and/or should have been on notice that the administration of GRANUFLO containing diacetate resulted in higher than normal post-dialysis bicarbonate levels.

111. As a result of their 2004 Retrospective Study Defendants were on notice and/or should have been on notice that the administration of GRANUFLO containing diacetate resulted in higher than normal pre-dialysis bicarbonate levels.

112. As a result of their 2004 Retrospective Study Defendants were on notice and/or should have been on notice that the administration of GRANUFLO containing diacetate resulted in an increase in metabolic alkalosis.

113. As a result of their 2004 Retrospective Study Defendants were on notice and/or should have been on notice that the administration of GRANUFLO containing diacetate resulted in a significant increase in metabolic alkalosis.

114. As a result of their 2004 Retrospective Study Defendants were on notice and/or should have been on notice that individuals not suffering from metabolic acidosis prior to dialysis were at an increased risk of suffering from metabolic alkalosis as a result of the administration of GRANUFLO.

115. As a result of their 2004 Retrospective Study, Defendants were on notice and/or should have been on notice that additional testing was necessary regarding the safety of their GRANUFLO.

116. As a result of their 2004 Retrospective Study, Defendants were on notice and/or should have been on notice that dialysis patients may have been receiving too many bicarbonates during dialysis as a result of their receipt of GRANUFLO.

117. As a result of their 2004 Retrospective Study Defendants were on notice and/or should have been on notice of the need to advise, instruct and/or warn all prescribing physicians and/or healthcare facilities that dialysis patients may be receiving too many types of bicarbonate during dialysis as a result of their receipt of GRANUFLO.

118. Defendants were on notice and/or should have been on notice of their obligation to report the results of their 2004 Retrospective Study to the FDA, the medical community, the Plaintiff, his treating physicians and healthcare providers and the public.

119. Upon information and belief, despite the results of their 2004 Retrospective Study and their knowledge of the severe health risks associated with their GRANUFLO, Defendants intentionally and willfully concealed their knowledge of these results and/or the increased severe health risks associated with their GRANUFLO from the FDA, the medical community, the Plaintiff, his treating physicians and healthcare providers and the public.

120. Upon information and belief, despite the results of their 2004 Retrospective Study and their knowledge of these results and/or the increased severe health risks associated with their GRANUFLO, Defendants failed to adequately and timely inform the FDA, the medical community, the Plaintiff, his treating physicians and healthcare providers and the public, regarding these results and/or risks.

121. Upon information and belief, despite the results of their 2004 Retrospective Study and their knowledge of these results and/or the increased severe health risks associated with their GRANUFLO, Defendants failed to advise and/or warn all doctors and/or other

healthcare providers treating patients with GRANUFLO to reduce the amount of bicarbonates being administered to and/or received by the patient during dialysis to take into account the additional bicarbonates that these individuals were receiving from GRANUFLO.

122. Upon information and belief, despite the results of their 2004 Retrospective Study and their knowledge of these results and/or the increased severe health risks associated with their GRANUFLO, Defendants failed to advise and/or warn all doctors and/or other healthcare providers treating patients with GRANUFLO to monitor more frequently the dialysis patient's post-dialysis bicarbonate levels.

123. Upon information and belief, despite the results of their 2004 Retrospective Study and their knowledge of these results and/or the increased severe health risks associated with their GRANUFLO, Defendants failed to advise and/or warn all doctors and/or other healthcare providers treating patients with GRANUFLO to monitor more frequently the dialysis patient's pre-dialysis bicarbonate levels.

124. Upon information and belief, despite the results of their 2004 Retrospective Study and their knowledge of these results and/or the increased severe health risks associated with their GRANUFLO, Defendants failed to advise and/or warn doctors he FDA, the medical community, the Plaintiff, his treating physicians and healthcare providers and the public that individuals not suffering from metabolic acidosis prior to dialysis were at an increased risk of suffering from metabolic alkalosis as a result of the administration of GRANUFLO.

125. Upon information and belief, despite the results of their 2004 Retrospective Study and their knowledge of the severe health risks associated with their GRANUFLO, Defendants failed to conduct additional testing regarding the safety of their GRANUFLO.

126. Upon information and belief, despite the results of their 2004 Retrospective Study and their knowledge of the severe health risks associated with their GRANUFLO, Defendants failed to advise, instruct and/or warn all prescribing physicians and/or healthcare facilities that dialysis patients may be receiving too many bicarbonates during dialysis as a result of their receipt of GRANUFLO.

127. On or about November 4, 2011 the Fresenius Defendants sent an Internal Memo ("Fresenius' Internal Memo") to certain Fresenius medical directors and attending physicians regarding the severe health risks associated with their NATURALYTE and/or GRANUFLO.

128. Within Fresenius' Internal Memo, the Fresenius Defendants identify a case-control study they performed to evaluate risk factors in hemodialysis patients who had suffered from cardiopulmonary arrest compared to other hemodialysis patients between January 1, 2010 and December 31, 2010.

129. The Fresenius Defendants did not notify the FDA of the case-control study identified within Fresenius' Internal Memo.

130. Upon information and belief, the Fresenius Defendants conducted the case-control study identified within Fresenius' Internal Memo because of increased reports of cardiac events being associated with their GRANUFLO.

131. According to Fresenius' Internal Memo, the results of the case-control study identified within Fresenius' Internal Memo revealed that for the patients receiving Defendants' NATURALYTE and/or GRANUFLO, there was a progressive shift towards higher pre-dialysis serum bicarbonate levels, implying that more patients were experiencing alkalosis prior to dialysis and an even higher percentage of patients were experiencing alkalosis post-dialysis.

132. According to Fresenius' Internal Memo, the results of the case-control study revealed that borderline elevated pre-dialysis bicarbonate levels and overt alkalosis were associated with six to eight fold greater risk of cardiopulmonary arrest and sudden cardiac death in the dialysis facility.

133. According to Fresenius' Internal Memo, the Fresenius Defendants stated "[i]n light of these troubling findings, we strongly recommend that physicians adjust dialysate bicarbonate prescriptions monthly for individual patients, with immediate attention to patients with serum pre-dialysis bicarbonate levels of >24 mEq/L."

134. Fresenius' Internal Memo was only sent to a limited number of medical directors and attending physicians employed by the Fresenius Defendants.

135. Upon information and belief, Fresenius' Internal Memo was not sent to the medical facilities at which the Plaintiff was administered and/or received NATURAL YTE and/or GRANUFLO.

136. Upon information and belief, Fresenius' Internal Memo was not sent to the Plaintiff's treating physicians who ordered and/or prescribed his dialysis treatments.

137. Fresenius' Internal Memo references previous internal memos that were sent to medical directors and attending physicians employed by the Fresenius Defendants regarding the severe health risks associated with NATURALYTE and/or GRANUFLO, which, at all relevant times, remained in the custody, control and possession of Defendants.

138. Upon information and belief, these previous internal memos were not sent to the medical facilities at which the Plaintiff was administered and/or received NATURALYTE and/or GRANUFLO.

139. Upon information and belief, these previous internal memos were not sent to the Plaintiff's treating physicians who ordered and/or prescribed his dialysis treatments.

140. Fresenius' Internal Memo references a Medical Staff Newsletter dated January 2010 that was made available to medical directors and attending physicians employed by the Fresenius Defendants and that discussed the severe health risks associated with NATURALYTE and/or GRANUFLO, which, at all relevant times, remained m the custody, control and possession of Defendants.

141. Upon information and belief, the Medical Staff Newsletter dated January 2010 was not sent to the medical facilities at which the Plaintiff was administered and/or received NATURALYTE and/or GRANUFLO.

142. Upon information and belief, Medical Staff Newsletter dated January 2010 was not sent to the Plaintiff's treating physicians who ordered and/or prescribed his dialysis treatments.

143. After the Fresenius Defendants learned and/or should have learned of the severe health risks associated with their NATURALYTE and/or GRANUFLO, the Fresenius Defendants intentionally and affirmatively elected not to report these risks to the FDA as required by law.

144. After the Fresenius Defendants learned and/or should have learned of the severe health risks associated with their NATURALYTE and/or GRANUFLO, the Fresenius Defendants intentionally and affirmatively elected not to report these risks to the entire medical community, the Plaintiff, his treating physicians and healthcare providers and the public at large.

145. Upon information and belief, the Fresenius Defendants colluded to hide, conceal and obscure information about the severe health risks associated with their NATURALYTE

and/or GRANUFLO so that dialysis patients, such as the Plaintiff, and their treating physicians and/or healthcare facilities would rely on and/or continue to use their NATURALYTE and/or GRANUFLO in dialysis treatments.

146. Upon information and belief, the Fresenius Defendants colluded to misrepresent information regarding the safety of their NATURALYTE and/or GRANUFLO so that dialysis patients, such as the Plaintiff, and their treating physicians and/or healthcare facilities would rely on and/or continue to use their NATURALYTE and/or GRANUFLO in dialysis treatments.

147. Upon information and belief, the Fresenius Defendants colluded to hide, conceal and obscure information about the severe health risks associated with their NATURALYTE and/or GRANUFLO in order to maintain their market share and to minimize and diffuse the legal risks for Fresenius.

148. Upon information and belief, the Fresenius Defendants colluded to misrepresent information regarding the safety of their NATURALYTE and/or GRANUFLO in order to maintain their market share and to minimize and diffuse the legal risks for Fresenius.

149. Upon information and belief, rather than informing the FDA, the medical community, the Plaintiff, his treating physicians and healthcare providers and the public at large of the severe health risks associated with their NATURALYTE and/or GRANUFLO, the Fresenius Defendants decided to manufacturer, market, promote, distribute and/or sell a new acid concentrate, Citrasate, to replace their NATURALYTE and/or GRANUFLO.

150. Upon information and belief, the Fresenius Defendants intended to advertise, market and promote the benefits of their new acid concentrate, Citrasate, so that treating physicians and medical facilities would switch to Citrasate from NATURALYTE and/or

GRANUFLO and, thus, the Fresenius Defendants could justify a discontinuance of their NATURALYTE and/or GRANUFLO for reasons other than product safety.

151. In reliance upon Defendants' misrepresentations, omissions and/or concealments as set forth herein, the Plaintiff, his treating physicians and/or his healthcare facilities used NATURALYTE and/or GRANUFLO.

152. Had the severe health risks associated with Defendants' NATURALYTE and/or GRANUFLO been properly and/or adequately disclosed, the Plaintiff, his treating physicians and/or his healthcare facilities would not have purchased and/or used NATURALYTE and/or GRANUFLO.

153. In or about March 2012 Fresenius' Internal Memo was anonymously submitted to the FDA.

154. In or about March 2012 the FDA discovered Defendants' knowledge and unlawful concealment of the severe health risks associated with their NATURALYTE and/or GRANUFLO.

155. In or about March 2012 the FDA discovered that the Fresenius Defendants had violated federal law by failing to report their knowledge of the severe health risks associated with their NATURALYTE and/or GRANUFLO.

156. As a result of the FDA's discovery of Defendants' knowledge and unlawful concealment of the severe health risks associated with their NATURALYTE and/or GRANUFLO, on or about March 27, 2012 Fresenius received an inquiry from the FDA regarding the severe health risks associated with their NATURALYTE and/or GRANUFLO.

157. Following the FDA's inquiry, on or about March 29, 2012, Defendants sent a vague and ambiguous two page memorandum entitled "Urgent Product Notification Letter" to

non-Fresenius dialysis clinics, hospitals and other customers notifying them of the risk of metabolic alkalosis associated with their NATURALYTE and/or GRANUFLO.

158. Upon information and belief, after further investigation conducted by the FDA into the severe health risks associated with their NATURALYTE and/or GRANUFLO, including Defendants' knowledge and unlawful concealment thereof, on July 10, 2012 the FDA issued a Class I recall of Defendants' NATURALYTE and/or GRANUFLO.

159. A Class I recall is a recall of dangerous or defective products that predictably could cause serious health problems or death.

160. A Class I recall is the most serious recall that can be issued by the FDA.

161. The Plaintiff, his treating physicians and/or healthcare facilities did not discover, nor did they have reason to discover, the serious and severe health risks associated with Defendants' NATURALYTE and/or GRANUFLO, until the products were recalled by the FDA on July 12, 2012.

C. The Fresenius Defendants

162. The Fresenius Defendants are the world's largest integrated providers of products and serves for individuals undergoing dialysis because of chronic kidney failure.

163. As vertically integrated companies, the Fresenius Defendants offer both dialysis clinics and products used in dialysis care, such as acid concentrates.

164. The Fresenius Defendants sell their products, including NATURALYTE and/or GRANUFLO, not only to their own dialysis clinics, but also to their "competitors."

165. The Fresenius Defendants are, and at all relevant times were, responsible for ensuring, through adequate warnings, training, instructing and monitoring, that their NATURALYTE and/or GRANUFLO were being properly used and/or administered by treating physicians, technicians and/or healthcare facilities.

166. In 2011, the Fresenius Defendants reported net revenue of $12.795 billion related to their dialysis services and products, with $8.15 billion in revenue attributed to North America (64%).

167. In 2010, the Fresenius Defendants reported net revenue of $12.053 billion related to their dialysis services and products, with $8.13 billion in revenue attributed to North America (67%).

168. The Fresenius Defendants have represented that they are committed to conducting their business activities in compliance with local laws and regulations, and that they seek to demonstrate professionalism, honesty and integrity in their business relationships with patients, customers, suppliers, the government, other payers, fellow employees, stockholders and the general public.

169. Despite the Fresenius Defendants' representations, upon discovering the serious health consequences and risks associated with their NATURALYTE and/or GRANUFLO, Defendants' intentionally, willfully, recklessly and/or negligently failed to advise and/or warn dialysis patients, including the Plaintiff, their customers (i.e. treating physicians, healthcare facilities, distributors), their suppliers, the government, other payers and/or the general public of said serious consequences and risks.

170. Despite the Fresenius Defendants' representations, upon discovering the serious health consequences and risks associated with their NATURALYTE and/or GRANUFLO, Defendants' permitted their NATURALYTE and/or GRANUFLO to be assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold without adequate warnings of the serious health consequences and risks associated with their NATURALYTE and/or GRANUFLO.

171. Despite the Fresenius Defendants' representations, upon discovering the serious health consequences and risks associated with their NATURALYTE and/or GRANUFLO, Defendants' permitted their NATURALYTE and/or GRANUFLO to be assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold without adequate instructions regarding the safe and proper use of their NATURALYTE and/or GRANUFLO.

172. Despite their knowledge of the serious health consequences and risks associated with their NATURALYTE and/or GRANUFLO, Defendants engaged in a marketing campaign to promote the purchase and/or sales of their NATURALYTE and/or GRANUFLO.

173. Based upon the results of their 2004 Retrospective Study, at all relevant times, Defendants advertised and/or marketed that the use of their GRANUFLO resulted in a 33% reduction in the prevalence of acidosis.

174. Defendants advertised and/or marketed GRANUFLO as less costly to transport to and/or store at healthcare facilities than other acid concentrates on the market.

175. Defendants successfully marketed their NATURALYTE and/or GRANUFLO throughout the United States by, among other things, conducting promotional campaigns that misrepresented the risks and benefits associated with their NATURALYTE and/or GRANUFLO in order to induce widespread use and consumption.

176. Defendants' misrepresentations regarding and/or promotions about their NATURALYTE and/or GRANUFLO were made by means of media advertisement, internet advertisements, press releases, sales literature, presentations, advertising campaigns, print ads, magazine ads and/or additional commercial media.

177. Upon information and belief, the Fresenius Defendants did not disclose the serious health consequences and risks associated with their NATURALYTE and/or GRANUFLO because they knew that physicians and/or healthcare facilities would not purchase their NATURALYTE and/or GRANUFLO, and, as a result, their sales would decline.

178. Upon information and belief, as a result of Defendants' advertising and/or marketing campaign, GRANUFLO experienced a steady increase in its market share since it was first approved in 2003 and, as of 2012, was used by the majority of hemodialysis patients in the United States.

179. Defendants' wanton, willful, fraudulent and/or reckless conduct, as set forth herein, demonstrates a complete disregard and reckless indifference for the health, safety and welfare of consumers and dialysis patients, including the Plaintiff, thus entitling Plaintiff to punitive damages so as to punish and deter such similar conduct in the future.

D. Injuries and Damages

180. As a result of Defendants' concealment and/or failure to advise and/or warn all doctors and/or other healthcare providers of the defectiveness and/or serious adverse health risks associated with their NATURALYTE and/or GRANUFLO as set forth herein, dialysis patients, such as the Plaintiff, who received Defendants' NATURALYTE and/or GRANUFLO experienced higher than normal post-dialysate bicarbonate levels.

181. As a result of Defendants' concealment and/or failure to advise and/or warn all doctors and/or other healthcare providers of the defectiveness and/or serious adverse health risks associated with their NATURALYTE and/or GRANUFLO as set forth herein, dialysis patients, such as the Plaintiff, who received Defendants' NATURALYTE and/or GRANUFLO experienced higher than normal pre-dialysate bicarbonate levels.

182. As a result of Defendants' concealment and/or failure to advise and/or warn doctors and/or other healthcare providers of the defectiveness and/or serious adverse health risks associated with their NATURALYTE and/or GRANUFLO as set forth herein, dialysis patients, such as the Plaintiff, who received Defendants' NATURALYTE and/or GRANUFLO have suffered and/or are suffering from metabolic alkalosis.

183. As a result of Defendants' concealment and/or failure to advise and/or warn doctors and/or other healthcare providers of the defectiveness and/or serious adverse health risks associated with their NATURALYTE and/or GRANUFLO as set forth herein, dialysis patients, such as the Plaintiff, who received Defendants' NATURALYTE and/or GRANUFLO have suffered from, are suffering from and/or will suffer from serious and grave health consequences, including but not limited to death, cardiopulmonary arrest, electrolyte imbalances, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, stroke, coma, and hypotension.

184. As a result of the defective nature of NATURALYTE and/or GRANUFLO, which was known and/or should have been known by the Fresenius Defendants at all relevant times, those persons who were administered, prescribed and/or ingested and/or were exposed to NATURALYTE and/or GRANUFLO, including Plaintiff, have suffered from, are suffering from and/or will suffer from serious and grave health consequences, including but not limited to death, cardiopulmonary arrest, electrolyte imbalances, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, heart attack, stroke, coma, and hypotension.

Federal Requirements

185. Pursuant to federal law, a medical device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or

controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. § 351.

186. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

187. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. *See* 21 U.S.C. § 360i.

188. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packaging, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with federal law. 21U.S.C. § 360j(f).

189. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR § 820 *et seq.* As explained in the Federal Register, because the Current Good Manufacturing Practice (CGMP) regulations must apply to a variety of medical devices, the regulations do not prescribe the details for how a manufacturer must produce a device. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured, and the manufacturing processes employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements set forth in the quality system regulations.

190. Pursuant to 21 CFR § 820.1(c), the failure to comply with any applicable provision in Part 820 renders a device adulterated under section 501(h) of the Federal Food Drug & Cosmetic Act ("the Act") (21 U.S.C. § 351).

191. Pursuant to 21 CFR § 820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. *See* 21 CFR § 820.3(v).

192. Pursuant to 21 CFR § 820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

193. Pursuant to 21 CFR § 820.30(a), each manufacturer shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

194. Pursuant to 21 CFR § 820.30(d), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

195. Pursuant to 21 CFR § 820.30(e), each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

196. Pursuant to 21 CFR § 820.30(f), each manufacturer shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

197. Pursuant to 21 CFR § 820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validations shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

198. Pursuant to 21 CFR § 820.30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

199. Pursuant to 21 CFR § 820.30(i), each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

200. Pursuant to 21 CFR § 820.70(a), each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe

any process controls necessary to ensure conformance to specifications. Such process controls shall include:

a. Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;

b. Monitoring and control of process parameters and component and device characteristics during production;

c. Compliance with specified reference standards or codes;

d. The approval of processes and process equipment; and

e. Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

201. Pursuant to 21 CFR § 820.70(b), each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure.

202. Pursuant to 21 CFR § 820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including periodic inspection of environmental control system(s) to verify that the system, including necessary equipment, is adequate and functioning properly.

203. Pursuant to 21 CFR § 820.70(e), each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.

204. Pursuant to 21 CFR § 820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirement and is appropriately

designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning and use.

205. Pursuant to 21 CFR § 820.70(h), each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality to ensure that it is removed or limited to an amount that does not adversely effect the device's quality.

206. Pursuant to 21 CFR § 820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate compute software for its intended use according to an established protocol.

207. Pursuant to 21 CFR § 820.72, each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained.

208. Pursuant to 21 CFR § 820.75(a), where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. "Process validation" means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. 21 CFR § 820.3(z)(1).

209. Pursuant to 21 CFR § 820.75(b), each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualified individuals.

210. Pursuant to 21 CFR § 820.90, each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

211. Pursuant to 21 CFR § 820.100, each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

a. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems;

b. Investigating the cause of nonconformities relating to product, processes, and the quality system;

c. Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

d. Verifying or validating the corrective and preventative action to ensure that such action is effective and does not adversely affect the finished device;

e. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

f. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

h. Submitting relevant information on identified quality problems, as well as corrective and preventative actions, for management review.

FRAUDULENT CONCEALMENT

212. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through affirmative misrepresentations and omissions, actively concealed from Plaintiff, physicians, the medical community, and the general public the true risks associated with NATURALYTE and/or GRANUFLO.

213. As a result of Defendants' actions, Plaintiff and physicians were unaware, and could not reasonably have known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

COUNT ONE

LOUISIANA PRODUCTS LIABILITY ACT

214. Plaintiff hereby restates and re-alleges each and every allegation set forth above, with the same force and effect as if herein repeated and set forth at length.

215. NATURALYTE and/or GRANUFLO proximately caused damage to the Plaintiff, which damage was caused by a characteristic of the product that rendered it unreasonably dangerous arising from a reasonably anticipated use of the product by Plaintiff, thus rendering Defendant liable to Plaintiff pursuant to LSA R.S. 9:2800.54.

216. NATURALYTE and/or GRANUFLO is unreasonably dangerous for the following reasons:

a. It is unreasonably dangerous in construction or composition as provided in LSA R.S. 9:2800.55;

b. It is unreasonably dangerous in design as provided in LSA R.S. 9:2800.56.

c. It is unreasonably dangerous because an accurate warning about the product was not provided as required by LSA R.S. 9:2800.57.

d. It is unreasonably dangerous because it does not conform to an express warranty of the manufacturer about the product as provided in LSA R.S. 9:2800.58.

217. The characteristics of NATURALYTE and/or GRANUFLO that render it unreasonably dangerous under LSA R.S. 9:2800.55, LSA R.S. 9:2800.56, and LSA R.S. 9:2800.57 et seq. existed at the time the product left the control of the manufacturer or resulted from a reasonably anticipated alteration or modification of the product.

218. For all of the reasons alleged herein, NATURALYTE and/or GRANUFLO was unreasonably dangerous in design at the time the product left the manufacturer's control in that:

a. There existed an alternate design for the product that was capable of preventing the Plaintiff's damages; and

b. The likelihood that the product's design would cause the Plaintiff's damages and the gravity of those damages outweigh the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product.

219. For all of the reasons alleged herein, NATURALYTE and/or GRANUFLO was unreasonably dangerous because an adequate warning about the product had not been provided and at the time the product left the manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide adequate warning that such characteristic and its dangers to users of the product.

220. Further, Defendants, before, during, and after the product left its control, acquired knowledge of the characteristic of the product that may cause damage and the danger of such characteristic (or, alternatively, Defendants would have acquired such knowledge if it had acted as reasonable prudent manufacturers), and thus are liable for damages suffered by Plaintiff which arose as a consequence of Defendants' failure to use reasonable care to provide an adequate warning of such characteristic and its dangers to users.

221. Defendants expressly warranted to the market, including Plaintiff, by and through statements made by Defendants or its authorized agents or sales representatives, orally and in publications, package inserts, advertisements and other materials to the health care and general community, that NATURALYTE and/or GRANUFLO was safe, effective, fit and proper for its intended use.

222. In using NATURALYTE and/or GRANUFLO, Plaintiff and his physicians relied on the skill; judgment, representations, and foregoing express warranties of the Defendants. These warranties and representations proved to be false because the product was not safe and was unfit for the uses for which it was intended.

COUNT TWO

VIOLATION OF WARRANTY OF REDHIBITION

223. Plaintiff hereby restates and re-alleges each and every allegation set forth above, with the same force and effect as if herein repeated and set forth at length.

224. Defendants were aware of the substantial risks from using NATURALYTE and/or GRANUFLO but failed to fully disclose the same.

225. Defendants, as the manufacturers of NATURALYTE and/or GRANUFLO, are deemed to be aware of its redhibitory defects pursuant to LSA-C.C. Article 2545.

226. Had Plaintiff been aware of the defects contained in NATURALYTE and/or GRANUFLO, Plaintiff would not have purchased or ingested NATURALYTE and/or GRANUFLO. This characteristic rendered it unfit for its intended purposes.

227. Defendant is liable to Plaintiff under the theory of redhibition as a consequence of the sale to Plaintiff of a product unfit for its intended use.

228. Plaintiff is entitled to the return of any purchase price paid, including but not limited to, insurance co-payments, interest on these amounts from the date of purchase, attorneys fees and costs, pecuniary and non-pecuniary damages, as well as any other legal and equitable relief to which Plaintiff may be entitled.

JURY DEMAND

229. Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays:

a) that process issue according to law;

b) that the Defendants be served with a copy of Plaintiff's Complaint and show cause why the prayers for relief requested by Plaintiff should not be granted;

c) that Plaintiff be granted a trial by jury in this matter;

d) that the Court enter judgment against the Defendants, jointly and severally, for all general and compensatory damages allowable to Plaintiff;

e) that the Court enter judgment against the Defendants for all special damages allowable to Plaintiff;

f) that the Court enter judgment against the Defendants for all equitable relief allowable to Plaintiff;

g) that the Court enter judgment against the Defendants for all declaratory relief allowable to Plaintiff;

h) that the Court enter judgment against the Defendants for all other relief allowable to Plaintiff;

i) that the Court award Plaintiff prejudgment interest on all damages;

j) that the Court award Plaintiff the costs and expenses in this litigation, including reasonable attorneys' fees and expert fees; and

k) that the Court award Plaintiff such other and further monetary, medical, equitable and declaratory relief as may be just and proper under the circumstances.

Dated: January 25, 2013

RESPECTFULLY SUBMITTED,

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CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Ronnie Glasper

(b) County of Residence of First Listed Plaintiff Concordia, Louisiana
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

James R. Dugan, II, The Dugan Law Firm, APLC, One Canal Place, 365 Canal Street, Suite 1000, New Orleans, LA 70130, Tel: (504) 648-0180

DEFENDANTS

Fresenius Medical Care Holdings, Inc., et al.

County of Residence of First Listed Defendant New York, New York
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 U.S.C. 1332

Brief description of cause:
Products Liability, Warranty of Redhibition

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 01/25/2013

SIGNATURE OF ATTORNEY OF RECORD /s/ James R. Dugan, II

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

Ronnie Glasper

Plaintiff(s)

v.

Fresenius Medical Care Holdings, Inc., et al.

Defendant(s)

Civil Action No. 2:13-cv-0147

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Fresenius Medical Care Holdings, Inc.
c/o CT Corporation System
111 Eighth Avenue
New York, NY 10011

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

James R. Dugan, II
The Dugan Law Firm, APLC
One Canal Place
365 Canal Street, Suite 100
New Orleans, LA 70130

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 2:13-cv-0147

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

Ronnie Glasper

Plaintiff(s)

v.

Fresenius Medical Care Holdings, Inc., et al.

Defendant(s)

Civil Action No. 2:13-cv-0147

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Fresenius Medical Care Holdings, Inc.
d/b/a Fresenius Medical Care North America
c/o CT Corporation System
111 Eighth Avenue
New York, NY 10011

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

James R. Dugan, II
The Dugan Law Firm, APLC
One Canal Place
365 Canal Street, Suite 100
New Orleans, LA 70130

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 2:13-cv-0147

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_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

Ronnie Glasper

Plaintiff(s)

v.

Fresenius Medical Care Holdings, Inc., et al.

Defendant(s)

Civil Action No. 2:13-cv-0147

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Fresenius USA, Inc.
c/o CT Corporation System
111 Eighth Avenue
New York, NY 10011

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

James R. Dugan, II
The Dugan Law Firm, APLC
One Canal Place
365 Canal Street, Suite 100
New Orleans, LA 70130

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 2:13-cv-0147

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify)*:

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

Ronnie Glasper

Plaintiff(s)

v.

Fresenius Medical Care Holdings, Inc., et al.

Defendant(s)

Civil Action No. 2:13-cv-0147

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Fresenius USA Manufacturing, Inc.
c/o CT Corporation System
111 Eighth Avenue
New York, NY 10011

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

James R. Dugan, II
The Dugan Law Firm, APLC
One Canal Place
365 Canal Street, Suite 100
New Orleans, LA 70130

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 2:13-cv-0147

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on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

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Date: _____

_____

Server's signature

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Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

Ronnie Glasper

Plaintiff(s)

v.

Fresenius Medical Care Holdings, Inc., et al.

Defendant(s)

Civil Action No. 2:13-cv-0147

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Fresenius USA Marketing, Inc.
c/o CT Corporation System
111 Eighth Avenue
New York, NY 10011

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

James R. Dugan, II
The Dugan Law Firm, APLC
One Canal Place
365 Canal Street, Suite 100
New Orleans, LA 70130

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

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Signature of Clerk or Deputy Clerk

Civil Action No. 2:13-cv-0147

PROOF OF SERVICE

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on *(date)* _____ , and mailed a copy to the individual's last known address; or

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designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____ _____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

Ronnie Glasper

Plaintiff(s)

v.

Fresenius Medical Care Holdings, Inc., et al.

Defendant(s)

Civil Action No. 2:13-cv-0147

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Fresenius Medical Care AG & CO. KGAA
61346 Bad Homburg
Germany

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

James R. Dugan, II
The Dugan Law Firm, APLC
One Canal Place
365 Canal Street, Suite 100
New Orleans, LA 70130

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 2:13-cv-0147

PROOF OF SERVICE

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❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

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on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

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❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

Ronnie Glasper

Plaintiff(s)

v.

Fresenius Medical Care Holdings, Inc., et al.

Defendant(s)

Civil Action No. 2:13-cv-0147

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Fresenius Medical Care Management, AG
61346 Bad Homburg
Germany

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

James R. Dugan, II
The Dugan Law Firm, APLC
One Canal Place
365 Canal Street, Suite 100
New Orleans, LA 70130

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CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 2:13-cv-0147

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_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

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❒ Other *(specify):*

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I declare under penalty of perjury that this information is true.

Date: _____

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Server's signature

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Printed name and title

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Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

Ronnie Glasper

Plaintiff(s)

v.

Fresenius Medical Care Holdings, Inc., et al.

Defendant(s)

Civil Action No. 2:13-cv-0147

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Fresenius SE & CO., KGAA
61346 Bad Homburg
Germany

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

James R. Dugan, II
The Dugan Law Firm, APLC
One Canal Place
365 Canal Street, Suite 100
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CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 2:13-cv-0147

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Date: _____

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Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

Ronnie Glasper

Plaintiff(s)

v.

Fresenius Medical Care Holdings, Inc., et al.

Defendant(s)

Civil Action No. 2:13-cv-0147

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Fresenius Management SE
61346 Bad Homburg
Germany

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

James R. Dugan, II
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One Canal Place
365 Canal Street, Suite 100
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CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

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on *(date)* _____ , and mailed a copy to the individual's last known address; or

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❒ Other *(specify):*

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Printed name and title

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Server's address

Additional information regarding attempted service, etc: