UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF INDIANA INDIANAPOLIS DIVISION

NATALIE S. COPASS,)	CAUSE NO.: 1:12-CV-1638-WTL-TAB
Plaintiff,))	JUDGE: WILLIAM T. LAWRENCE
v. NEW ENGLAND COMPOUNDING PHARMACY INC.,d/b/a NEW ENGLAND)))))	<u>ANSWER AND AFFIRMATIVE</u> <u>DEFENSES OF DEFENDANT</u> AMERIDOSE, LLC TO PLAINTIFF'S
COMPOUNDING CENTER, AMERIDOSE INC., ALAUNUS PHARMACEUTICALS,)	<u>COMPLAINT</u>
GREGORY CONIGLIARO, and BARRY J. CADDEN,))	
Defendants.))	

Defendant Ameridose, LLC, improperly captioned Ameridose Inc., by and through its undersigned counsel, hereby answers Plaintiff's Complaint for Damages as follows:

1. To the extent that "Contaminated Steroid Injection" means methylprednisolone acetate (MPA) in Paragraph 1 and throughout Plaintiff's Complaint, Defendant generally denies that it manufactured, compounded, sold and/or distributed MPA. Furthermore, to the extent that Defendant makes any injectable steroid products, there have been no contaminations. The remaining allegations require no response.

2. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 2.

3. Defendant denies the allegations against it in Paragraph 3 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants. Defendant is not required to respond to the allegations in Paragraph 3 that set forth

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legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

4. Defendant is not required to respond to the allegations of Paragraph 4 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

FACTUAL BACKGROUND

5. Defendant denies the allegations in Paragraph 5 against it and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

6. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 6.

7. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 7.

8. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 8.

9. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 9.

PARTIES, JURISDICTION AND VENUE

10. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 10.

11. The allegations in Paragraph 11 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 11 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

12. The allegations in Paragraph 12 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 12 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

13. The allegations in Paragraph 13 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 13 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

14. Defendant denies that it is a Massachusetts corporation, but states that it is a Massachusetts domestic Limited Liability Company with a principal place of business located at 205 Flanders Road, Westborough, MA 01581, County of Worcester. Defendant denies that its primary business is "unit dose repackaging." Because "managed" is undefined, Defendant denies the remaining allegations in Paragraph 14.

15. The allegations in Paragraph 15 are not directed to this Defendant so no response is necessary. To the extent one is deemed required, Defendant denies the allegations against it in Paragraph 15 and lacks knowledge or information sufficient to form a belief about the truth of these allegations as to the other Defendants.

16. Defendant admits that Barry J. Cadden and Gregory Conigliaro are part owners of Ameridose. Defendant denies the remaining allegations against it in Paragraph 16 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

17. Defendant admits the allegations in Paragraph 17.

18. Defendant admits the allegations in Paragraph 18.

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19. Defendant denies that Barry J. Cadden and Gregory Conigliaro are the majority shareholders of Ameridose. Defendant is not required to respond to the remaining allegations in Paragraph 19 that are not directed to it.

20. Defendant admits that it has essentially the same owners as Defendants NECC and Alaunus. Defendant is not required to respond to the allegations in Paragraph 20 that set forth legal conclusions. However, to the extent that the allegations may be construed against it, Defendant denies them.

21. No response is required for Paragraph 21.

22. Defendant is not required to respond to the allegations in Paragraph 22 that set forth legal conclusions. However, to the extent that the allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

23. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 23 related to Plaintiff's residency and treatment. Defendant is not required to respond to the allegations in Paragraph 23 that set forth legal conclusions. However, to the extent that the allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

FACTUAL ALLEGATIONS

24. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 24 because it did not manufacture, compound, sell or distribute MPA.

25. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 25.

26. Defendant denies the allegations against it in Paragraph 26 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

27. Defendant denies the allegations against it in Paragraph 27 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

28. Defendant denies that it manufactured, compounded, sold or distributed MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 28 as to the other Defendants.

29. Defendant denies the allegations against it in Paragraph 29 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

30. Defendant denies that it manufactured, compounded, sold or distributed MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 30 as to the other Defendants.

31. Defendant denies the allegations against it in Paragraph 31 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

32. Defendant admits that it has FDA approval to act as a pharmaceutical manufacturer. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 32.

33. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 33.

34. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 34.

35. Defendant denies the allegations against it in Paragraph 35 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

36. Defendant denies the allegations against it in Paragraph 36 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

- a. Defendant denies that it tested MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 36(a) as to the other Defendants.
- b. Defendant denies that it sold MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 36(b) as to the other Defendants.
- c. Defendant denies that it manufactured, compounded, sold or distributed MPA.
 Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 36(c) as to the other Defendants.
- d. Defendant denies the allegations against it in Paragraph 36(d) and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

37. Defendant denies the allegations against it in Paragraph 37 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

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38. Defendant denies that it produced and sold MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 38 as to the other Defendants.

39. Defendant is not required to respond to the allegations in Paragraph 39 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 39 as to the other Defendants.

40. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 40.

41. The allegations in Paragraph 41 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 41.

42. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 42.

43. Defendant denies the allegations against it in Paragraph 43 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

FACTUAL ALLEGATIONS AS TO THE NAMED PLAINTIFF

44. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 44.

45. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 45.

46. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 46.

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47. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 47.

48. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 48.

49. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 49.

50. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 50.

51. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 51.

<u>FIRST CLAIM FOR RELIEF</u> (Strict Product Liability – Failure to Warn)

52. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

53. Defendant is not required to respond to the allegations in Paragraph 53 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 53 as to the other Defendants.

54. Defendant is not required to respond to the allegations in Paragraph 54 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 54 as to the other Defendants.

55. Defendant denies the allegations against it in Paragraph 55 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

56. Defendant denies the allegations against it in Paragraph 56 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

57. Defendant denies the allegations against it in Paragraph 57 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

58. Defendant denies the allegations against it in Paragraph 58 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

59. Defendant denies the allegations against it in Paragraph 59 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

60. Defendant denies the allegations against it in Paragraph 60 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

61. Defendant denies the allegations against it in Paragraph 61 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

62. Defendant denies the allegations against it in Paragraph 62 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

63. Defendant denies the allegations against it in Paragraph 63 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

64. Defendant denies the allegations against it in Paragraph 64 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

65. Defendant is not required to respond to the allegations in Paragraph 65 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 65 as to the other Defendants.

- a. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 65(a).
- b. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 65(b).
- c. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 65(c).
- d. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 65(d).

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RESPONDING TO WHEREFORE CLAUSE

Defendant denies entitlement to the relief requested in the Complaint. Defendant demands a trial by jury.

<u>SECOND CLAIM FOR RELIEF</u> (Strict Liability – Dangerously Defective Product)

66. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

67. Defendant denies the allegations against it in Paragraph 67 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

68. Defendant denies the allegations against it in Paragraph 68 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

69. Defendant is not required to respond to the allegations in Paragraph 69 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 69 as to the other Defendants.

70. Defendant is not required to respond to the allegations in Paragraph 70 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 70 as to the other Defendants.

71. Defendant is not required to respond to the allegations in Paragraph 71 that set forth legal conclusions. However, to the extent that such allegations may be construed against it,

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Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 71 as to the other Defendants.

72. Defendant is not required to respond to the allegations in Paragraph 72 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 72 as to the other Defendants.

73. Defendant is not required to respond to the allegations in Paragraph 73 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 73 as to the other Defendants.

- a. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 73(a).
- b. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 73(b).
- c. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 73(c).
- d. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 73(d).

RESPONDING TO WHEREFORE CLAUSE

Defendant denies entitlement to the relief requested in the Complaint. Defendant demands a trial by jury.

THIRD CLAIM FOR RELIEF (Negligence)

74. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

75. Defendant is not required to respond to the allegations in Paragraph 75 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 75 as to the other Defendants.

76. Defendant denies the allegations against it in Paragraph 76 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

77. Defendant is not required to respond to the allegations in Paragraph 77 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 77 as to the other Defendants.

- a. Defendant denies the allegations against it in Paragraph 77(a) and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
- b. Defendant denies the allegations against it in Paragraph 77(b) and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

- c. Defendant denies the allegations against it in Paragraph 77(c) and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
- d. Defendant denies the allegations against it in Paragraph 77(d) and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
- e. Defendant denies the allegations against it in Paragraph 77(e) and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
 - Defendant denies the allegations against it in Paragraph 77(e)(i) and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
 - Defendant denies the allegations against it in Paragraph 77(e)(ii) and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
 - iii. Defendant denies the allegations against it in Paragraph 77(e)(iii) and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
 - iv. Defendant denies the allegations against it in Paragraph 77(e)(iv) and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

- v. Defendant denies the allegations against it in Paragraph 77(e)(v) and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
- f. Defendant denies the allegations against it in Paragraph 77(f) and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
- g. Defendant denies the allegations against it in Paragraph 77(g) and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
- h. Defendant denies the allegations against it in Paragraph 77(h) and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

78. Defendant denies the allegations against it in Paragraph 78 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

79. Defendant denies the allegations against it in Paragraph 79 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

80. Defendant denies the allegations against it in Paragraph 80 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

81. Defendant is not required to respond to the allegations in Paragraph 81 that set forth legal conclusions. However, to the extent that such allegations may be construed against it,

Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 81 as to the other Defendants.

- a. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 81(a).
- b. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 81(b).
- c. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 81(c).
- d. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 81(d).

RESPONDING TO WHEREFORE CLAUSE

Defendant denies entitlement to the relief requested in the Complaint. Defendant demands a trial by jury.

FOURTH CLAIM FOR RELIEF (Breach of Implied Warranty)

82. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

83. Defendant denies the allegations against it in Paragraph 83 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

84. Defendant denies the allegations against it in Paragraph 84 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

85. Defendant denies the allegations against it in Paragraph 85 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

86. Defendant denies the allegations against it in Paragraph 86 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

87. Defendant denies the allegations against it in Paragraph 87 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

88. Defendant denies the allegations against it in Paragraph 88 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

89. Defendant denies the allegations against it in Paragraph 89 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

90. Defendant denies the allegations against it in Paragraph 90 and and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants and the allegations as to Plaintiff.

RESPONDING TO WHEREFORE CLAUSE

Defendant denies entitlement to the relief requested in the Complaint. Defendant demands a trial by jury.

<u>FIFTH CLAIM FOR RELIEF</u> (Negligent Infliction of Emotional Distress)

91. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

92. Defendant denies the allegations against it in Paragraph 92 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

93. Defendant denies the allegations against it in Paragraph 93 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

94. Defendant is not required to respond to the allegations in Paragraph 94 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 94 as to the other Defendants.

95. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 95.

RESPONDING TO WHEREFORE CLAUSE

Defendant denies entitlement to the relief requested in the Complaint. Defendant demands a trial by jury.

DEFENSES AND AFFIRMATIVE DEFENSES

During the course of litigation, a number of defenses and/or affirmative defenses may become available to Defendant. To the extent any of the following are available and may apply, notice is hereby given of the following:

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1. The Complaint fails to state a claim or cause of action cognizable in law or equity against Defendant Ameridose.

2. The Complaint fails to allege a cognizable claim for breach of any applicable standard for the practice of pharmacy as to Defendant Ameridose.

3. Plaintiff lacks standing to sue Defendant Ameridose.

4. Defendant did not make the product in question and has no liability here since it is a separate entity not responsible for the acts of the other Defendants.

5. The allegations of the Complaint do not adequately set forth the elements required to overcome the presumption of corporate separateness under applicable state law.

6. The Complaint fails to sufficiently identify a preparation compounded or manufactured by this Defendant.

7. The alleged injuries or damages may have been proximately caused by one or more unforeseeable, independent intervening or superseding events beyond the control of and unrelated to the conduct of Defendant, including Plaintiff's contributory negligence, pre-existing medical condition, and assumption of the risk.

8. Adequate warnings and information were available to the medical profession, including any prescribing or administering healthcare provider.

9. Damages, if any, have not been appropriately mitigated.

10. Plaintiff's alleged injuries and/or damages, if any, were caused or contributed to by entities other than this Defendant and those named as Defendants in this action. Fault and a percentage of liability must be apportioned to all who caused or contributed to the Plaintiff's alleged injuries according to the Indiana Product Liability Act, specifically Ind. Code 34-20-8-1,

and the Indiana Comparative Fault Act, specifically Ind. Code 34-51-2-8, Ind. Code 34-51-2-11 and Ind. Code 34-51-2-14.

WHEREFORE, Defendant demands Judgment of this Court:

- a. dismissing the Complaint against it, with prejudice;
- awarding to Defendant the costs, expenses, and fees associated with defending this action; and
- c. granting such other and further relief, both legal and equitable, that the Court deems just and proper.

Dated: December 13, 2012

Respectfully submitted,

<u>s/ Knight S. Anderson</u> Knight S. Anderson (17216-53) TUCKER ELLIS LLP 925 Euclid Avenue, Suite 1150 Cleveland, OH 44115-1414 Telephone: 216.696.2761 Facsimile: 216.592.5009 E-mail: <u>knight.anderson@tuckerellis.com</u>

Attorney for Defendant Ameridose, LLC

CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing has been filed with the Clerk of the Court on December 13, 2012 using the ECF system that sent notification of this filing to the following:

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<u>/s/Knight S. Anderson</u> Attorney for Defendant Ameridose, LLC