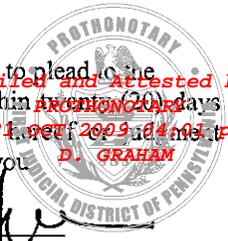


NOTICE TO PLEAD

You are hereby notified to plead in the
within New Matter within ~~30~~ ¹⁴ days
of the date of service ~~of the~~ ^{per 2009 rules}
may be entered against you. **D. GRAHAM**



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Actavis Totowa LLC
Actavis Inc.
Actavis Elizabeth LLC

IN RE: DIGITEK LITIGATION

: COURT OF COMMON PLEAS
:
: PHILADELPHIA COUNTY
:
: MARCH TERM, 2009
:
: NO. 5166
:
: JURY TRIAL DEMANDED

**DEFENDANTS ACTAVIS TOTOWA LLC, ACTAVIS INC., AND
ACTAVIS ELIZABETH LLC'S ANSWER TO PLAINTIFFS' GENERAL
MASTER LONG-FORM COMPLAINT WITH NEW MATTER**

Defendants Actavis Totowa LLC ("Actavis Totowa"), Actavis Inc. ("Actavis")
(incorrectly sued as Actavis US), and Actavis Elizabeth LLC ("Actavis Elizabeth") by and
through their counsel, Segal, McCambridge, Singer, Mahoney, Ltd., hereby submit this Answer
with New Matter to Plaintiffs' General Master Long-Form Complaint ("Plaintiffs' Complaint")
and in support thereof aver as follows:

ANSWER TO PLAINTIFFS

1. The allegations in Paragraph 1 of Plaintiffs' Complaint require no response from Defendants. To the extent a response is required, Defendants deny the allegations for want of knowledge and lack of information.

2. Defendants admit that Actavis Totowa initiated a voluntary nationwide recall of Digitek® on April 25, 2008. Defendants deny the remaining allegations in Paragraph 2 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

ANSWER TO DEFENDANTS

3. Defendants admit that Actavis Group hf is a generic pharmaceutical company with its principal place of business in Iceland. Defendants also admit that Actavis Group hf is the parent corporation of Actavis Group PTC ehf, which is the parent of Actavis Inc, which is the sole member of Actavis Totowa and Actavis Elizabeth. Defendants deny the remaining allegations in Paragraph 3 of Plaintiffs' Complaint, specifically denying that Actavis Group hf had any involvement in the activities regarding Digitek® as alleged in the corresponding paragraph.

4. Defendants admit that Actavis Totowa, formerly known as Amide Pharmaceutical, Inc., is a Delaware limited liability company with its principal place of business in New Jersey. Defendants deny the remaining allegations in Paragraph 4 of Plaintiffs' Complaint, specifically denying that Actavis Group hf had any involvement in the activities regarding Digitek® as alleged in the corresponding paragraph.

5. Defendants admit that Actavis Inc. is a Delaware corporation with its principal place of business in New Jersey. Defendants deny the remaining allegations in Paragraph 5 of

Plaintiffs' Complaint, specifically denying that Actavis Group hf had any involvement in the activities regarding Digitek® as alleged in the corresponding paragraph.

6. Defendants admit that Actavis Elizabeth is a Delaware limited liability company with its principal place of business in New Jersey. Defendants deny the remaining allegations in Paragraph 6 of Plaintiffs' Complaint, specifically denying that Actavis Group hf had any involvement in the activities regarding Digitek® as alleged in the corresponding paragraph.

7. Defendants deny the allegations in Paragraph 7 of Plaintiffs' Complaint, specifically denying that Actavis US is an entity capable of being sued.

8. The allegations in Paragraph 8 of Plaintiffs' Complaint require no response from Defendants. To the extent a response is required, Defendants deny the allegations for want of knowledge and lack of information.

9. Defendants admit that at all times relevant to the captioned matter, Actavis Totowa manufactured Digitek® pursuant to an Abbreviated New Drug Application (hereinafter "ANDA"), but deny the remaining allegations in Paragraph 9 of Plaintiffs' Complaint, including subparagraphs (a) through (d), specifically denying that Actavis Group hf had any involvement in the activities regarding Digitek® as alleged in the corresponding paragraph.

10. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 10 of Plaintiffs' Complaint, and therefore deny the same.

11. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 11 of Plaintiffs' Complaint, and therefore deny the same.

12. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 12 of Plaintiffs' Complaint, and therefore deny the same.

13. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 13 of Plaintiffs' Complaint, and therefore deny the same.

14. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 14 of Plaintiffs' Complaint, and therefore deny the same.

15. The allegations in Paragraph 15 of Plaintiffs' Complaint require no response from Defendants. To the extent a response is required, Defendants deny the allegations for want of knowledge and lack of information.

16. Defendants admit that at all times relevant to the captioned matter, Mylan Pharmaceuticals Inc. distributed Digitek® under a "Bertek" label and UDL Laboratories, Inc. distributed Digitek® under a "UDL" label, but deny the remaining allegations in Paragraph 16 of Plaintiffs' Complaint, including subparagraphs (a) through (d).

ANSWER TO JURISDICTION AND VENUE

17. The allegations in Paragraph 17 of Plaintiffs' Complaint require no response from Defendants. To the extent a response is required, Defendants deny for want of knowledge and lack of information the allegations in Paragraph 17 of Plaintiffs' Complaint.

18. Defendants admit that at all times relevant to the captioned matter, Actavis Totowa manufactured Digitek®. Defendants deny the remaining allegations in Paragraph 18 of Plaintiffs' Complaint.

19. The allegations in Paragraph 19 of Plaintiffs' Complaint require no response from Defendants. To the extent a response is required, Defendants deny for want of knowledge and lack of information the allegations in Paragraph 19 of Plaintiffs' Complaint, specifically denying that Plaintiffs are entitled to any relief as set forth in the corresponding paragraph.

ANSWER TO FACTUAL ALLEGATIONS

20. Defendants admit that Digitek® is a cardiac glycoside indicated for the treatment of atrial fibrillation and congestive heart failure. Defendants deny the remaining allegations in Paragraph 20 of Plaintiffs' Complaint.

21. Defendants admit that Digitek® is a registered trademark of Mylan Bertek Pharmaceuticals Inc.

22. Defendants admit that Digitek® is indicated for the treatment of atrial fibrillation and congestive heart failure. Defendants deny the remaining allegations in Paragraph 22 of Plaintiffs' Complaint.

23. Defendants deny the allegations in Paragraph 23 of Plaintiffs' Complaint.

24. Defendants admit that the Food and Drug Administration ("FDA") regulates the sale of Digitek® in the United States and approved 0.125 mg and 0.250 mg dosages, but deny the remaining allegations in Paragraph 24 of Plaintiffs' Complaint.

25. Defendants admit that the FDA approved the sale of 0.125 mg and 0.250 mg dosages of Digitek®, but deny the remaining allegations in Paragraph 25 of Plaintiffs' Complaint.

26. Defendants admit that the FDA approved the sale of 0.125 mg and 0.250 mg dosages of Digitek®, but deny the remaining allegations in Paragraph 26 of Plaintiffs' Complaint.

27. Defendants admit that at all times relevant to the captioned matter, Actavis Totowa manufactured Digitek® pursuant to an ANDA, but deny the remaining allegations in Paragraph 27 of Plaintiffs' Complaint.

28. Defendants admit that the FDA issued a letter to Actavis Totowa dated August 15, 2006. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 28 of Plaintiffs' Complaint.

29. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 29 of Plaintiffs' Complaint, and therefore deny the same.

30. Defendants admit that the FDA issued a letter to Actavis Totowa dated August 15, 2006. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 30 of Plaintiffs' Complaint.

31. Defendants admit that the FDA issued a letter to Actavis Totowa dated August 15, 2006. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 31 of Plaintiffs' Complaint.

32. Defendants admit that the FDA issued a letter to Actavis Totowa dated August 15, 2006. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 32 of Plaintiffs' Complaint.

33. Defendants admit that the FDA issued a letter to Actavis Totowa dated August 15, 2006. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 33 of Plaintiffs' Complaint.

34. Defendants admit that the FDA issued a letter to Actavis Totowa dated February 1, 2007. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 34 of Plaintiffs' Complaint.

35. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 35 of Plaintiffs' Complaint, and therefore deny the same.

36. Defendants admit that the FDA issued a letter to Actavis Totowa dated February 1, 2007. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 36 of Plaintiffs' Complaint.

37. Defendants admit that the FDA issued a letter to Actavis Totowa dated February 1, 2007. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 37 of Plaintiffs' Complaint.

38. Defendants admit that the FDA issued a letter to Actavis Totowa dated February 1, 2007 and a prior inspection report form. These documents speak for themselves and, on that basis, Defendants deny the remaining allegations in Paragraph 38 of Plaintiffs' Complaint.

39. Defendants admit that the FDA issued a letter to Actavis Totowa dated February 1, 2007. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 39 of Plaintiffs' Complaint.

40. Defendants admit that the FDA issued a letter to Actavis Totowa dated February 1, 2007. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 40 of Plaintiffs' Complaint.

41. Defendants admit that the FDA issued a letter to Actavis Totowa dated February 1, 2007. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 41 of Plaintiffs' Complaint.

42. Defendants admit that the FDA issued a letter to Actavis Totowa dated February 1, 2007. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 42 of Plaintiffs' Complaint, including subparagraphs (e) through (h).

43. Defendants admit that the FDA issued a letter to Actavis Totowa dated February 1, 2007. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 43 of Plaintiffs' Complaint.

44. Defendants admit that the FDA issued a letter to Actavis Totowa dated February 1, 2007. The letter speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 44 of Plaintiffs' Complaint.

45. Defendants admit that at all times relevant to the captioned matter, Actavis Totowa manufactured Digitek® pursuant to an ANDA, Mylan Pharmaceuticals Inc. distributed Digitek® under a "Bertek" label, and UDL Laboratories, Inc. distributed Digitek® under a "UDL" label. Defendants deny the remaining allegations in Paragraph 45 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

46. Defendants admit that digoxin overdose and digitalis toxicity can cause serious injury and even death, but deny that Plaintiffs and/or Decedents exhibited such symptoms or conditions as a result of their alleged use of Digitek®. Defendants deny the remaining allegations in Paragraph 46 of Plaintiffs' Complaint.

47. Defendants admit that on April 25, 2008, Actavis Totowa initiated a voluntary nationwide recall of all lots of Digitek®. Defendants deny the remaining allegations in Paragraph 47 of Plaintiffs' Complaint for want of knowledge and lack of information.

48. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 48 of Plaintiffs' Complaint, and therefore deny the same.

49. Defendants admit that, on August 1, 2008, Actavis Totowa initiated a voluntary retail-level recall of all drug products manufactured at its Little Falls, New Jersey facility

following an FDA inspection that revealed operations which did not meet the FDA's or Actavis' good manufacturing practices. Defendants deny the remaining allegations in Paragraph 49 of Plaintiffs' Complaint.

50. Defendants admit that, in December 2008, Actavis Totowa reached an agreement with the FDA, settling the issues identified by the Department of Justice in its complaint. The Consent Decree that sets forth the agreement speaks for itself and, on that basis, Defendants deny the remaining allegations in Paragraph 50 of Plaintiffs' Complaint.

51. Defendants deny the allegations in Paragraph 51 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

52. Defendants admit that digoxin overdose and digitalis toxicity can cause serious injury and even death, but deny that Plaintiffs and/or Decedents exhibited such symptoms or conditions as a result of their alleged use of Digitek®.

53. The Digitek® label speaks for itself and, on that basis, Defendants deny the allegations in Paragraph 53 of Plaintiffs' Complaint.

54. Defendants admit that digoxin overdose and digitalis toxicity can cause serious injury and even death, but deny that Plaintiffs and/or Decedents exhibited such symptoms or conditions as a result of their alleged use of Digitek®. Defendants deny the remaining allegations in Paragraph 54 of Plaintiffs' Complaint.

55. Defendants admit that digoxin overdose and digitalis toxicity can cause serious injury and even death, but deny that Plaintiffs and/or Decedents exhibited such symptoms or conditions as a result of their alleged use of Digitek®. Defendants deny the remaining allegations in Paragraph 55 of Plaintiffs' Complaint.

56. The Digitek® label speaks for itself and, on that basis, Defendants deny the allegations in Paragraph 56 of Plaintiffs' Complaint.

57. The Digitek® label speaks for itself and, on that basis, Defendants deny the allegations contained in Paragraph 57 of Plaintiffs' Complaint.

58. Defendants deny the allegations in Paragraph 58 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective and that Digitek® was the proximate cause of the injuries and damages alleged in Paragraph 58 of Plaintiffs' Complaint.

59. Defendants admit that Actavis Totowa was subject only to those duties imposed by applicable law and deny that any such duty was breached. Defendants deny the remaining allegations in Paragraph 59 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

60. Defendants deny the allegations in Paragraph 60, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

61. Defendants deny the allegations in Paragraph 61 of Plaintiffs' Complaint.

62. Defendants deny the allegations in Paragraph 62 of Plaintiffs' Complaint.

63. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 63 of Plaintiffs' Complaint, and therefore deny the same.

64. Defendants deny the allegations in Paragraph 64 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective and that Digitek® was the proximate cause of the injuries and damages alleged in Paragraph 64 of Plaintiffs' Complaint.

65. Defendants deny the allegations in Paragraph 65 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedent were defective, that Digitek® was the proximate cause of the injuries and damages alleged in Paragraph 65 of Plaintiffs' Complaint, and that Plaintiffs are entitled to any relief as set forth in the corresponding paragraph.

66. Defendants deny the allegations in Paragraph 66 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective, that Digitek® was the proximate cause of the injuries and damages alleged in Paragraph 66 of Plaintiffs' Complaint, and that Plaintiffs are entitled to any relief as set forth in the corresponding paragraph.

67. Defendants deny the allegations in Paragraph 67 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective and that Digitek® was the proximate cause of the injuries and damages alleged in Paragraph 67 of Plaintiffs' Complaint.

ANSWER TO CLAIMS FOR RELIEF

COUNT 1
PRODUCT LIABILITY
NEGLIGENCE

68. In response to Paragraph 68 of Plaintiffs' Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 67 of Plaintiffs' Complaint, as if fully set forth herein.

69. Defendants admit that at all times relevant to the captioned matter, Actavis Totowa manufactured Digitek® pursuant to an ANDA, Mylan Pharmaceuticals Inc. distributed Digitek® under a "Bertek" label and UDL Laboratories, Inc. distributed Digitek® under a

“UDL” label. Defendants deny the remaining allegations in Paragraph 69 of Plaintiffs’ Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

70. Defendants admit that Actavis Totowa was subject only to those duties imposed by applicable law and deny that any such duty was breached. Defendants deny the remaining allegations in Paragraph 70 of Plaintiffs’ Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

71. Defendants deny the allegations in Paragraph 71 of Plaintiffs’ Complaint, including subparagraphs (a) through (l), specifically denying that any duty was breached and that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

72. Defendants deny the allegations in Paragraph 72 of Plaintiffs’ Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective and that Digitek® was the proximate cause of the injuries and damages alleged in Paragraph 72 of Plaintiffs’ Complaint.

73. Defendants deny the allegations in Paragraph 73 of Plaintiffs’ Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

74. Defendants admit that Digitek® tablets were expected to reach patients without a substantial change in their condition from the time they were sold. Defendants deny the remaining allegations in Paragraph 74 of Plaintiffs’ Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

75. Defendants deny the allegations in Paragraph 75 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

76. The allegations in Paragraph 76 of Plaintiffs' Complaint are legal conclusions that do not require a response from Defendants. To the extent a response is required, Defendants deny the allegations in Paragraph 76 of Plaintiffs' Complaint.

77. Defendants deny the allegations in Paragraph 77 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

78. Defendants deny the allegations in Paragraph 78 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Plaintiff were defective.

79. Defendants deny the allegations in Paragraph 79 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

80. Defendants deny the allegations in Paragraph 80 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

81. Defendants deny the allegations in Paragraph 81 of Plaintiffs' Complaint, specifically denying that Plaintiffs are entitled to any relief as set forth in the corresponding paragraph.

82. Defendants deny the allegations in Paragraph 82 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged

in Paragraph 82 of Plaintiffs' Complaint, and that Plaintiffs are entitled to the relief requested in the unnumbered Paragraph following Paragraph 82 of Plaintiffs' Complaint.

COUNT 2
FAILURE TO ADEQUATELY WARN

83. In response to Paragraph 83 of Plaintiffs' Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 82 of Plaintiffs' Complaint, as if fully set forth herein.

84. Defendants admit that at all times relevant to the captioned matter, Actavis Totowa manufactured Digitek® pursuant to an ANDA, Mylan Pharmaceuticals Inc. distributed Digitek® under a "Bertek" label, and UDL Laboratories, Inc. distributed Digitek® under a "UDL" label. Defendants admit that Actavis Totowa was subject only to those duties imposed by applicable law and deny that any such duty was breached. Defendants deny the remaining allegations in Paragraph 84 of Plaintiffs' Complaint.

85. Defendants admit that at all times relevant to the captioned matter, Actavis Totowa manufactured Digitek® pursuant to an ANDA, Mylan Pharmaceuticals Inc. distributed Digitek® under a "Bertek" label, and UDL Laboratories, Inc. distributed Digitek® under a "UDL" label. Defendants deny the remaining allegations in Paragraph 85 of Plaintiffs' Complaint.

86. Defendants deny the allegations in Paragraph 86 of Plaintiffs' Complaint.

87. Defendants deny the allegations in Paragraph 87 of Plaintiffs' Complaint.

88. Defendants admit that at all times relevant to the captioned matter, Actavis Totowa manufactured Digitek® pursuant to an ANDA, Mylan Pharmaceuticals Inc. distributed Digitek® under a "Bertek" label, and UDL Laboratories, Inc. distributed Digitek® under a "UDL" label. Defendants deny the remaining allegations in Paragraph 88 of Plaintiffs' Complaint.

Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

89. Defendants deny the allegations in Paragraph 89 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Paragraph 89 of Plaintiffs' Complaint, and that Plaintiffs are entitled to the relief requested in the unnumbered Paragraph following Paragraph 89 of Plaintiffs' Complaint.

COUNT 3
PRODUCT LIABILITY – MANUFACTURING DEFECT

90. In response to Paragraph 90 of Plaintiffs' Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 89 of Plaintiffs' Complaint, as if fully set forth herein.

91. Defendants admit that at all times relevant to the captioned matter, Actavis Totowa manufactured Digitek® pursuant to an ANDA, Mylan Pharmaceuticals Inc. distributed Digitek® under a "Bertek" label and UDL Laboratories, Inc. distributed Digitek® under a "UDL" label. Defendants deny the remaining allegations in Paragraph 91 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

92. Defendants admit that Digitek® tablets were expected to reach patients without a substantial change in their condition from the time they were sold. Defendants deny the remaining allegations in Paragraph 92 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

93. Defendants deny the allegations in Paragraph 93 of Plaintiffs' Complaint, including subparagraphs (a) through (d), specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

94. Defendants deny the allegations in Paragraph 94 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Paragraph 94 of Plaintiffs' Complaint and that Plaintiffs are entitled to the relief requested in the unnumbered paragraph following Paragraph 94 of Plaintiffs' Complaint.

COUNT 4
BREACH OF EXPRESS WARRANTY

95. In response to Paragraph 95 of Plaintiffs' Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 94 of Plaintiffs' Complaint, as if fully set forth herein.

96. Defendants admit that Digitek® was marketed as a safe and effective product at all times relevant to the captioned matter. Defendants deny the remaining allegations in Paragraph 96 of Plaintiffs' Complaint, specifically denying the existence of any warranties in favor of, or representations to, Plaintiffs and/or Decedents by Defendants regarding Digitek®.

97. Defendants deny the allegations in Paragraph 97 of Plaintiffs' Complaint, specifically denying the existence of any warranties in favor of, or representations to, Plaintiffs and/or Decedents by Defendants regarding Digitek® and that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

98. Defendants admit that Actavis Totowa was subject only to those duties imposed by applicable law and deny that any such duty was breached. Defendants deny the remaining allegations in Paragraph 98 of Plaintiffs' Complaint, including subparagraphs (a) through (e), specifically denying the existence or breach of any warranties in favor of, or representations to, Plaintiffs and/or Decedents by Defendants regarding Digitek®.

99. Defendants deny the allegations in Paragraph 99 of Plaintiffs' Complaint, specifically denying the existence of any warranties in favor of, or representations to, Plaintiffs

and/or Decedents by Defendants regarding Digitek® and that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

100. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 100 of Plaintiffs' Complaint, and therefore deny the same, specifically denying the existence or breach of any warranties in favor of, or representations to, Plaintiffs and/or Decedents by Defendants regarding Digitek® and that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

101. Defendants admit that Actavis Totowa was subject only to those duties imposed by applicable law and deny that any such duty was breached. Defendants deny the remaining allegations in Paragraph 101 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Plaintiffs and/or Decedents were defective.

102. Defendants deny the allegations in Paragraph 102 of Plaintiffs' Complaint, specifically denying the existence or breach of any warranties in favor of, or representations to, Plaintiffs and/or Decedents by Defendants regarding Digitek® and that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

103. Defendants deny the allegations in Paragraph 103 of Plaintiffs' Complaint, specifically denying the existence or breach of any warranties in favor of, or representations to, Plaintiffs and/or Decedents by Defendants regarding Digitek®, that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective, and that Digitek® was the proximate cause of the injuries and damages alleged in the corresponding paragraph.

104. Defendants deny the allegations in Paragraph 104 of Plaintiffs' Complaint, specifically denying the existence or breach of any warranties in favor of, or representations to, Plaintiffs and/or Decedents by Defendants regarding Digitek®, that any Digitek® tablets

ingested by Plaintiffs and/or Decedents were defective, and that Digitek® was the proximate cause of the injuries and damages alleged in the corresponding paragraph.

105. Defendants deny the allegations in Paragraph 105 of Plaintiffs' Complaint, specifically denying the existence or breach of any warranties in favor of, or representations to, Plaintiffs and/or Decedents by Defendants regarding Digitek®, that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective, that Digitek® was the proximate cause of the injuries and damages alleged in the corresponding paragraph, and that Plaintiffs are entitled to the relief requested in the unnumbered paragraph following Paragraph 105 of Plaintiffs' Complaint.

COUNT 5
BREACH OF IMPLIED WARRANTY

106. In response to Paragraph 106 of Plaintiffs' Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 105 of Plaintiffs' Complaint, as if fully set forth herein.

107. Defendants admit that at all times relevant to the captioned matter, Actavis Totowa manufactured Digitek® pursuant to an ANDA, Mylan Pharmaceuticals Inc. distributed Digitek® under a "Bertek" label and UDL Laboratories, Inc. distributed Digitek® under a "UDL" label. Defendants admit that Digitek® is indicated for the treatment of atrial fibrillation and congestive heart failure. Defendants deny the remaining allegations in Paragraph 107 of Plaintiffs' Complaint.

108. Defendants admit that Digitek® was marketed as a safe and effective product at all times relevant to the captioned matter. Defendants deny the remaining allegations in Paragraph 108 of Plaintiffs' Complaint, specifically denying the existence of any warranties in favor of, or representations to, Plaintiffs and/or Decedents by Defendants regarding Digitek®.

109. Defendants deny the allegations in Paragraph 109 of Plaintiffs' Complaint.

110. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 110 of Plaintiffs' Complaint, and therefore deny the same.

111. Defendants deny the allegations in Paragraph 111 of Plaintiffs' Complaint, specifically deny that any Digitek® tablets used by Plaintiffs and/or Decedents were defective.

112. Defendants deny the allegations in Paragraph 112 of Plaintiffs' Complaint, specifically denying the existence or breach of any warranties in favor of, or representations to, Plaintiffs and/or Decedents by Defendants regarding Digitek® and that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

113. Defendants deny the allegations in Paragraph 113 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in the corresponding paragraph and that Plaintiffs are entitled to the relief requested in the unnumbered paragraph following Paragraph 113 of Plaintiffs' Complaint.

COUNT 6
MISREPRESENTATION AND SUPPRESSION BY DEFENDANTS

114. In response to Paragraph 114 of Plaintiffs' Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 113 of Plaintiffs' Complaint, as if fully set forth herein.

115. Defendants deny the allegations in Paragraph 115 of Plaintiffs' Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek® and that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

116. Defendants deny the allegations in Paragraph 116 of Plaintiffs' Complaint, including subparagraphs (i) through (v), specifically denying the existence of any representations

to Plaintiffs and/or Decedents by Defendants regarding Digitek® and that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

117. Defendants deny the allegations in Paragraph 117 of Plaintiffs' Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek®.

118. Defendants deny the allegations in Paragraph 118 of Plaintiffs' Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek®.

119. Defendants deny the allegations in Paragraph 119 of Plaintiffs' Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek®.

120. Defendants deny the allegations in Paragraph 120 of Plaintiffs' Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek®.

121. Defendants admit that Actavis Totowa was subject only to those duties imposed by applicable law and deny that any such duty was breached. Defendants deny the remaining allegations in Paragraph 121 of Plaintiffs' Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek® and that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

122. Defendants deny the allegations in Paragraph 122 of Plaintiffs' Complaint.

123. Defendants deny the allegations in Paragraph 123 of Plaintiffs' Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by

Defendants regarding Digitek® and that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

124. Defendants deny the allegations in Paragraph 124 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in the corresponding paragraph and that Plaintiffs are entitled to the relief requested in the unnumbered paragraph following Paragraph 124 of Plaintiffs' Complaint.

COUNT 7
NEGLIGENT MISREPRESENTATION

125. In response to Paragraph 125 of Plaintiffs' Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 124 of Plaintiffs' Complaint, as if fully set forth herein.

126. Defendants deny the allegations in Paragraph 126 of Plaintiffs' Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek®.

127. Defendants deny the allegations in Paragraph 127 of Plaintiffs' Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek®.

128. Defendants deny the allegations in Paragraph 128 of Plaintiffs' Complaint.

129. Defendants admit that Actavis Totowa was subject only to those duties imposed by applicable law and deny that any such duty was breached. Defendants deny the remaining allegations in Paragraph 129 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective.

130. Defendants deny the allegations in Paragraph 130 of Plaintiffs' Complaint.

131. Defendants deny the allegations in Paragraph 131 of Plaintiffs' Complaint, specifically denying the existence of any representations to Plaintiffs and/or Decedents by Defendants regarding Digitek® and that Digitek® was the proximate cause of the injuries and damages alleged in the corresponding paragraph, and that Plaintiffs are entitled to the relief requested in the unnumbered paragraph following Paragraph 131 of Plaintiffs' Complaint.

COUNT 8
WRONGFUL DEATH

132. In response to Paragraph 132 of Plaintiffs' Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 131 of Plaintiffs' Complaint, as if fully set forth herein.

133. Defendants deny the allegations in Paragraph 133 of Plaintiffs' Complaint, specifically denying the existence or breach of any warranties in favor of, or representations to, Plaintiffs and/or Decedents by Defendants regarding Digitek®, that any Digitek® tablets ingested by Plaintiffs and/or Decedents were defective, that Digitek® was the proximate cause of the injuries and damages alleged in the corresponding paragraph, and that Plaintiffs are entitled to the relief requested in the unnumbered paragraph following Paragraph 133 of Plaintiffs' Complaint.

COUNT 9
SURVIVAL ACTION

134. In response to Paragraph 134 of Plaintiffs' Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 133 of Plaintiffs' Complaint, as if fully set forth herein.

135. The allegations in Paragraph 135 of Plaintiffs' Complaint do not require a response from Defendants. To the extent a response is required, Defendants deny the allegations in Paragraph 135 of Plaintiffs' Complaint.

136. Defendants deny the allegations in Paragraph 136 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in the corresponding paragraph and that Plaintiffs are entitled to the relief requested in the unnumbered paragraph following Paragraph 136 of Plaintiffs' Complaint.

COUNT 10
LOSS OF CONSORTIUM

137. In response to Paragraph 137 of Plaintiffs' Complaint, Defendants reallege and incorporate by reference their answers to Paragraphs 1 through 136 of Plaintiffs' Complaint, as if fully set forth herein.

138. Defendants lack knowledge and information sufficient to form a belief as to the truth of the allegations in Paragraph 138 of Plaintiffs' Complaint, and therefore deny the same.

139. Defendants lack knowledge and information sufficient to form a belief as to the truth of the allegations in Paragraph 139 of Plaintiffs' Complaint, and therefore deny the same.

140. Defendants deny the allegations in Paragraph 140 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in the corresponding paragraph and that Plaintiffs are entitled to the relief requested in the unnumbered paragraph following Paragraph 140 of Plaintiffs' Complaint.

ANSWER TO JURY DEMAND

141. The allegations in Plaintiffs' Jury Demand require no answer from Defendants. To the extent an answer is required, Defendants deny the allegations for want of knowledge and lack of information.

ANSWER TO PRAYER FOR RELIEF

142. Defendants deny the allegations in the unnumbered paragraph in Plaintiffs' Prayer for Relief, including subparagraphs (1) through (11), specifically denying that Plaintiffs are entitled to any relief as set forth in Plaintiffs' Prayer for Relief, that any Digitek® tablets used by Plaintiffs and/or Decedents were defective, and that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint. By way of further response, Defendants deny any and all allegations in Plaintiffs' Complaint not specifically admitted hereinabove, including any and all allegations requesting relief. Defendants request judgment in their favor, including costs and attorneys' fees.

NEW MATTER

143. Plaintiffs' Complaint fails to state a claim upon which relief can be granted as to some or all of Plaintiffs' claims.

144. Plaintiffs' claims are barred by the applicable statute of limitations, statute of repose, and/or the equitable doctrines of laches, estoppel, statutory and regulatory compliance.

145. Defendants hereby raise, assert, and preserve their defense of lack of personal jurisdiction.

146. Defendants hereby raise, assert, and preserve their defense of insufficiency of process.

147. Defendants hereby raise, assert, and preserve their defense of insufficiency of service of process.

148. Plaintiffs' Complaint has failed to name necessary and indispensable parties.

149. Plaintiffs' claims are barred by the doctrines of informed consent, release, and waiver.

150. The injuries and damages allegedly suffered in this action, which are denied, may have been caused in whole or in part by the own culpable conduct, intentional acts, contributory negligence, assumption of risk, and want of care, of Plaintiffs and/or Decedents.

151. Some or all of Plaintiffs' claims are barred by the doctrine of superseding and/or intervening cause.

152. The injuries and damages allegedly suffered in this action, which are denied, were due to an allergic, idiosyncratic, or idiopathic reaction to the product at issue in this case, or by an unforeseeable illness, unavoidable accident, or preexisting condition, without any negligence or culpable conduct by Defendants.

153. The injuries and damages allegedly suffered in this action, which are denied, were caused in whole or in part by the acts (wrongful or otherwise), negligence, sole fault, misuse, abuse, modification, alteration, omission, or fault of one or more persons or entities over whom Defendants exercise no control and for whom Defendants are not legally responsible, including, without limitation, Plaintiffs and/or Decedents.

154. Plaintiffs' claims are barred by the "state of the art" and "state of scientific knowledge" defenses.

155. Plaintiffs' claims are barred by the learned intermediary doctrine.

156. Plaintiffs' claims against Defendants are expressly and/or impliedly preempted by federal law; including but not limited to, the regulations promulgated by the U.S. Food and Drug Administration as codified in Chapter 21 of the Code of Federal Regulations. *See* 21 U.S.C. § 301 *et seq.*; *see also* 71 Fed. Reg. 3922 (Jan. 24, 2006).

157. Plaintiffs' claims are barred because Defendants complied with all applicable state and federal statutes regarding the product in question including the requirements and

regulations promulgated by the U.S. Food and Drug Administration as codified in Chapter 21 of the Code of Federal Regulations. Specifically, Plaintiffs' failure to warn claims are preempted by federal Food and Drug regulations specifying that the warning language that can be used by generic manufacturers must be exactly the same as that approved by FDA for use by the innovator manufacturer. Plaintiffs' design defect claims are also preempted because the FDA made a specific determination that Digitek® was safe and effective and that its benefits outweighed its risks. In the event that Plaintiffs' claims are not barred, Defendants are entitled to a presumption that the product in question is free from any defect or defective condition and that its labeling was adequate.

158. Defendants did not make nor did they breach any express or implied warranties and/or breach any warranties created by law. To the extent that Plaintiffs rely on any theory of breach of warranty, such claims are barred by applicable law, by the lack of privity between Plaintiffs and/or Decedents and Defendants, and/or by the failure of Plaintiffs to give Defendants timely notice of the alleged breach of warranty. Defendants further specifically plead as to any breach of warranty claim all affirmative defenses under the Uniform Commercial Code, as enacted in the Commonwealth of Pennsylvania and any other state whose law is deemed to apply in this case.

159. Plaintiffs' claims are barred by comments *j* and *k* to Section 402A of the Restatement (Second) of Torts.

160. Plaintiffs' claims are barred by Sections 2, 4, 6(c), and 6(d) of the Restatement (Third) of Torts: Products Liability.

161. Plaintiffs' product liability claims are barred because the benefits of the relevant product outweighed its risks.

162. Plaintiffs' claims are barred in whole or in part because the product at issue was at all times properly prepared, packaged, and distributed, and was not defective or unreasonably dangerous.

163. An imposition of punitive damages in this case against Defendants is barred to the extent that the manner in which such punitive damages are calculated violates the Constitution of the United States or the Constitution of the Commonwealth of Pennsylvania and any other state whose law is deemed to apply in this case.

164. Any award of punitive damages in this case against Defendants is barred to the extent that the amount of such an award violates the Constitution of the United States or the Constitution of the Commonwealth of Pennsylvania and any other state whose law is deemed to apply in this case.

165. Defendants are entitled to a set-off for all amounts paid, payable by, or available from collateral sources, including write-offs/write-downs in charges.

166. The damages recoverable by Plaintiffs, if any, must be reduced by any amount of damages legally caused by Plaintiffs and/or Decedents' failure to mitigate such damages in whole or in part.

167. Plaintiffs' claims are barred, in whole or in part, because Defendants did not owe or breach a duty to Plaintiffs and/or Decedents.

168. Plaintiffs' claims are barred by Plaintiffs' and/or Decedents' failure to comply with conditions precedent to their right to recover.

169. The claims asserted in Plaintiffs' Complaint are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of Defendants' conduct.

170. Plaintiffs' and/or Decedents' alleged damages were not caused by any failure to warn on the part of Defendants.

171. Defendants had no duty to warn about any possible dangers in using their products which were not known at the time of manufacture and sale of the products.

172. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

173. The claims asserted in Plaintiffs' Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

174. If Plaintiffs and/or Decedents were exposed to any product manufactured, produced, sold, or supplied by Defendants, which is specifically denied, said exposure was *de minimis* and insufficient as a matter of law to establish with a reasonable degree of probability that the product at issue caused Decedents' or Plaintiffs' injuries.

175. Plaintiffs may not recover on the claims pleaded in the Complaint because the damages sought are too speculative and remote.

176. Digitek®, if in fact ingested by Plaintiffs and/or Decedents, did not cause or contribute to any alleged injuries.

177. Digitek® was not unreasonably dangerous in formulation or composition at the time it left Defendants' control as it did not deviate in any way from Defendants' and the FDA's mandatory specifications.

178. Digitek® was not unreasonably dangerous for failure to conform to an express warranty.

179. Digitek® was not unreasonably dangerous for failure to conform to any implied warranty.

180. Plaintiffs' causes of action are barred in whole or in part by Plaintiffs' comparative negligence.

181. Plaintiffs and/or Decedents were knowledgeable users and, therefore, Defendants are not legally responsible for either the acts or omissions of the knowledgeable users or misinformation or lack of information provided to them by others.

182. Plaintiffs have no standing to bring this action and/or to seek the relief requested in the Plaintiffs' Complaint.

183. Plaintiffs' claims of breach of express warranty and breach of implied warranty are barred because there was no privity between Defendants and Plaintiffs and/or Decedents.

184. Plaintiffs' claims of breach of express warranty are barred because any alleged warranty was not the basis of the bargain.

185. Plaintiffs' claims of breach of express warranty are barred because Plaintiff has failed to allege any statements made by Defendants.

186. Plaintiffs have failed to state a claim upon which attorneys' fees and/or costs can be awarded.

187. Plaintiffs and/or Decedents failed to exercise ordinary care under the circumstances and such failure was the substantial cause of the occurrence that caused injury or damage, if any, to Plaintiffs and/or Decedents.

188. To the extent that Plaintiffs seek punitive damages, such damages are barred because Defendants' conduct was not fraudulent, malicious, willful, or wanton.

189. Some or all of Plaintiffs' claims are barred by reason of spoliation of evidence.

190. Some or all of Plaintiffs' claims should be dismissed due to misjoinder.

191. Plaintiffs' claims are barred in whole or part because they have been filed in an improper venue.

192. Plaintiffs' claims are barred in whole or part because they have been filed in an inconvenient forum or *forum non conveniens*.

193. Plaintiffs' claims are barred and/or limited pursuant to the provisions of the Comparative Negligence Act, 42 Pa. Cons. Stat. Ann. § 7102 *et. seq.*, the relevant portions of which are incorporated herein by reference as though the same were fully set forth at length herein.

194. Defendants at all times discharged their duties through appropriate and adequate warnings.

195. Defendants hereby reserve the right to amend their answer to assert any other defenses, affirmative or otherwise, that may become available during discovery proceedings in this case.

WHEREFORE, Defendants Actavis Totowa LLC, Actavis Inc., and Actavis Elizabeth LLC respectfully request judgment to be entered in their favor and against all other parties together with cost and fees and any such other relief as the Court may deem just and appropriate.

Segal McCambridge Singer & Mahoney, Ltd.

By: 

Walter H. Swayze, III, Esquire
Megan E. Grossman, Esquire

Attorneys for Defendants
Actavis Totowa LLC, Actavis Inc., and
Actavis Elizabeth LLC

Date: 10/21/09

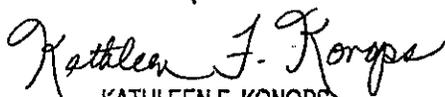
VERIFICATION

I, Chris Young, hereby state that I am familiar with this action and verify that statements made in the foregoing Answer to Plaintiffs' General Master Long-Form Complaint are true and correct to the best of my knowledge, information and belief. The undersigned understands that the statements therein are made subject to penalties of 18 Pa.C.S. § 4904, relating to unsworn falsification to authorities.

By: 
CHRIS YOUNG

Managing Director of Operations
Actavis Totowa LLC

Sworn to and subscribed
before me this 21st day of
October, 2009.

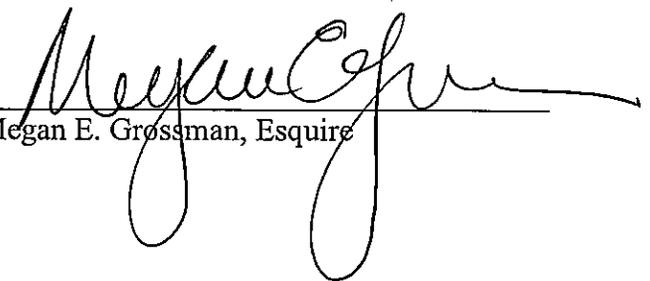

KATHLEEN F. KONOPS
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires 12/07/2010.

CERTIFICATION OF SERVICE

It is hereby certified that I electronically filed the foregoing Answer to Plaintiffs' General Master Long-Form Complaint on the date indicated below. Also, a true and correct copy of same was served via first class mail, postage pre-paid, upon the following counsel on the date indicated below:

Peter Miller, Esquire
The Miller Firm, LLC
The Sherman Building
108 Railroad Avenue
Orange, VA 22960

Segal McCambridge Singer & Mahoney, Ltd.

By: 
Megan E. Grossman, Esquire

Date: 10/21/09