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ATTORNEYS FOR DEFENDANT MERCK & CO., INC.

	:	
	:	SUPERIOR COURT OF NEW JERSEY
	:	LAW DIVISION
Plaintiff(s),	:	ATLANTIC COUNTY
	:	
vs.	:	DOCKET NO.
	:	
MERCK & CO., INC.,	:	VIOXX® LITIGATION
	:	CASE NO.: 619
Defendant.	:	CIVIL ACTION
	:	AMENDED MASTER LONG FORM
	:	ANSWER, AFFIRMATIVE
	:	DEFENSES AND JURY DEMAND
	:	ON BEHALF OF DEFENDANT
	:	MERCK & CO., INC.

Defendant Merck & Co., Inc. ("Merck"), with its principal place of business located at One Merck Drive, Whitehouse Station, New Jersey 08889-0100, by and through its undersigned counsel, amends its answer to the Master Long Form Complaint as follows:

1. States that paragraph 1 of the Master Long Form Complaint contains a declaratory statement as to which no responsive pleading is required.
2. Denies each and every allegation contained in paragraph 2 of the Master Long Form Complaint.

RESPONSE TO "PARTIES - PLAINTIFF"

3. Denies each and every allegation contained in paragraph 3 of the Master Long Form Complaint, except admits that plaintiffs purport to state a claim for damages, but denies that there is any legal or factual basis for such relief.

4. States that paragraph 4 of the Master Long Form Complaint contains a declaratory statement as to which no responsive pleading is required.

RESPONSE TO "DEFENDANT"

5. Denies each and every allegation contained in paragraph 5 of the Master Long Form Complaint, except admits that Merck is a New Jersey Corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey.

6. Denies each and every allegation contained in paragraph 6 of the Master Long Form Complaint, except admits that Merck is a leading research-driven pharmaceutical products and services company that researches, discovers, manufactures and markets a broad range of innovative pharmaceutical products to improve human health. Merck further admits that it manufactured, marketed and distributed the prescription medicine VIOXX® until Merck voluntarily withdrew VIOXX® from the market on September 30, 2004.

RESPONSE TO "FACTS COMMON TO ALL COUNTS"

7. Denies each and every allegation contained in paragraph 7 of the Master Long Form Complaint, except admits that Merck manufactured, marketed, and distributed the prescription medicine VIOXX® until Merck voluntarily withdrew VIOXX® from the market on September 30, 2004, that VIOXX® is Merck's trade name for rofecoxib, which reduces pain and inflammation and that the mechanism of action is believed to be due to inhibition of prostaglandin synthesis via inhibition of an enzyme known as cyclooxygenase-2 ("COX-2").

8. Denies each and every allegation contained in paragraph 8 of the Master Long Form Complaint, except admits that Merck manufactured, marketed, and distributed the prescription medicine VIOXX® until Merck voluntarily withdrew VIOXX® from the market on September 30, 2004, and that VIOXX® reduces pain and inflammation and that the mechanism of action is believed to be due to inhibition of prostaglandin synthesis via inhibition of an enzyme known as COX-2.

9. Denies each and every allegation contained in paragraph 9 of the Master Long Form Complaint, except admits that Merck sought and received Food and Drug Administration (“FDA”) approval to manufacture and market the prescription medicine VIOXX® and respectfully refers the Court to the referenced New Drug Application (“NDA”) for its actual language and full text.

10. Denies each and every allegation contained in paragraph 10 of the Master Long Form Complaint, except admits that Merck sought and received FDA approval to manufacture and market the prescription medicine VIOXX® and respectfully refers the Court to the referenced NDA for its actual language and full text.

11. Denies each and every allegation contained in paragraph 11 of the Master Long Form Complaint, except admits that Merck sought and received FDA approval to manufacture and market the prescription medicine VIOXX® and respectfully refers the Court to the prescribing information for VIOXX® for its indicated uses.

12. Denies each and every allegation contained in paragraph 12 of the Master Long Form Complaint, except admits that plaintiffs appear to have accurately quoted a portion of the prescribing information for VIOXX® approved by the FDA and respectfully refers the Court to the referenced document for its actual language and full text.

13. Denies each and every allegation contained in paragraph 13 of the Master Long Form Complaint, except admits that plaintiffs appear to have accurately quoted a portion of the prescribing information for VIOXX® approved by the FDA and respectfully refers the Court to the referenced document for its actual language and full text.

14. Denies each and every allegation contained in paragraph 14 of the Master Long Form Complaint, except admits that Merck scientists participated in the VIGOR study involving VIOXX® and respectfully refers the Court to the referenced study for its actual conclusions and full text.

15. Denies each and every allegation contained in paragraph 15 of the Master Long Form Complaint, except admits that Merck scientists participated in the VIGOR study involving VIOXX® and respectfully refers the Court to the referenced study for its actual conclusions and full text.

16. Denies each and every allegation contained in paragraph 16 of the Master Long Form Complaint, and respectfully refers the Court to the referenced studies for their actual language and full text.

17. Denies each and every allegation contained in paragraph 17 of the Master Long Form Complaint, except admits that Merck manufactured, marketed, and distributed the prescription medicine VIOXX® until Merck voluntarily withdrew VIOXX® from the market on September 30, 2004, and respectfully refers the Court to the prescribing information for VIOXX® for its indicated uses.

18. Denies each and every allegation contained in paragraph 18 of the Master Long Form Complaint, and respectfully refers the Court to the referenced study for its actual language and full text.

19. Denies each and every allegation contained in paragraph 19 of the Master Long Form Complaint, and respectfully refers the Court to the referenced study for its actual language and full text.

20. Denies each and every allegation contained in paragraph 20 of the Master Long Form Complaint, and respectfully refers the Court to the referenced studies for their actual language and full text.

21. Denies each and every allegation contained in paragraph 21 of the Master Long Form Complaint, except admits that Merck received a letter from a regulatory review officer at the FDA in September 2001 and respectfully refers the Court to that letter for its actual language and full text.

22. Denies each and every allegation contained in paragraph 22 of the Master Long Form Complaint, except admits that plaintiffs appear to have accurately quoted a portion of the referenced letter and respectfully refers the Court to the referenced letter for its actual language and full text.

23. Denies each and every allegation contained in paragraph 23 of the Master Long Form Complaint, except admits that plaintiffs appear to have accurately quoted a portion of the referenced letter and respectfully refers the Court to the referenced letter for its actual language and full text.

24. Denies each and every allegation contained in paragraph 24 of the Master Long Form Complaint, except admits that on or about April 11, 2002 the FDA approved certain changes to the VIOXX® prescribing information and the so-called “Dear Doctor Letter” and respectfully refers the Court to the referenced prescribing information and letter for their actual language and full text.

25. Denies each and every allegation contained in paragraph 25 of the Master Long Form Complaint, except admits that on or about April 11, 2002 the FDA approved certain changes to the prescribing information for VIOXX® and respectfully refers the Court to the referenced prescribing information for its actual language and full text.

26. Denies each and every allegation contained in paragraph 26 of the Master Long Form Complaint, except admits that on or about April 11, 2002 the FDA approved a so-called "Dear Doctor" letter regarding VIOXX® and respectfully refers the Court to the referenced letter for its actual language and full text.

27. Denies each and every allegation contained in paragraph 27 of the Master Long Form Complaint, except admits that on or about April 11, 2002 the FDA approved a revised Patient Product Information Sheet for VIOXX® and respectfully refers the Court to the referenced Patient Product Information Sheet for its actual language and full text.

28. Denies each and every allegation contained in paragraph 28 of the Master Long Form Complaint.

29. Denies each and every allegation contained in paragraph 29 of the Master Long Form Complaint.

30. Denies each and every allegation contained in paragraph 30 of the Master Long Form Complaint, except admits that Merck produced an Annual Report in 2001 and respectfully refers the Court to that report for its actual language and full text.

31. Denies each and every allegation contained in paragraph 31 of the Master Long Form Complaint, except admits that Merck produced an 8-K filing in January 2001 and respectfully refers the Court to that report for its actual language and full text.

32. Denies each and every allegation contained in paragraph 32 of the Master Long Form Complaint and avers that the FDA approved VIOXX® as safe and effective for its intended uses subject to the information contained in its prescribing information and avers further that notwithstanding the voluntary withdrawal of VIOXX® on September 30, 2004 it would have been possible to continue to market VIOXX® with labeling that would incorporate the new data that led Merck to voluntarily withdraw VIOXX®, but given the availability of alternative therapies, and the questions raised by the data, Merck concluded that a voluntary withdrawal was the responsible course to take.

**RESPONSE TO “COUNT I PRODUCTS
LIABILITY—DEFECTIVE DESIGN (N.J.S.A. 2A:58C-2 *et seq.*)**

33. With respect to the allegations contained in paragraph 33 of the Master Long Form Complaint, repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 32 of this Answer with the same force and effect as though set forth here in full.

34. Denies each and every allegation contained in paragraph 34 of the Master Long Form Complaint, except admits that Merck manufactured, marketed, and distributed the prescription medicine VIOXX® until Merck voluntarily withdrew VIOXX® from the market on September 30, 2004.

35. Denies each and every allegation contained in paragraph 35 of the Master Long Form Complaint.

36. Denies each and every allegation contained in paragraph 36 of the Master Long Form Complaint, except admits that Merck manufactured, marketed, and distributed the prescription medicine VIOXX® until Merck voluntarily withdrew VIOXX® from the market on September 30, 2004.

37. Denies each and every allegation contained in paragraph 37 of the Master Long Form Complaint and avers that the FDA approved VIOXX® as safe and effective for its intended uses subject to the information contained in its prescribing information and avers further that notwithstanding the voluntary withdrawal of VIOXX® on September 30, 2004 it would have been possible to continue to market VIOXX® with labeling that would incorporate the new data that led Merck to voluntarily withdraw VIOXX®, but given the availability of alternative therapies, and the questions raised by the data, Merck concluded that a voluntary withdrawal was the responsible course to take.

38. The allegations contained in paragraph 38 of the Master Long Form Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph.

39. Denies each and every allegation contained in paragraph 39 of the Master Long Form Complaint.

40. Denies each and every allegation contained in paragraph 40 of the Master Long Form Complaint.

WHEREFORE, Merck respectfully demands judgment dismissing plaintiffs' Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

**RESPONSE TO "COUNT II PRODUCTS
LIABILITY—FAILURE TO WARN (N.J.S.A. 2A:58C-2 et seq.)"**

41. With respect to the allegations contained in paragraph 41 of the Master Long Form Complaint, repeats and realleges each and every admission, denial, averment, and

statement contained in paragraphs 1 through 40 of this Answer with the same force and effect as though set forth here in full.

42. Denies each and every allegation contained in paragraph 42 of the Master Long Form Complaint, except admits that Merck manufactured, marketed, and distributed the prescription medicine VIOXX® until Merck voluntarily withdrew VIOXX® from the market on September 30, 2004.

43. Denies each and every allegation contained in paragraph 43 of the Master Long Form Complaint and avers that the FDA approved VIOXX® as safe and effective for its intended uses subject to the information contained in its prescribing information and avers further that notwithstanding the voluntary withdrawal of VIOXX® on September 30, 2004 it would have been possible to continue to market VIOXX® with labeling that would incorporate the new data that led Merck to voluntarily withdraw VIOXX®, but given the availability of alternative therapies, and the questions raised by the data, Merck concluded that a voluntary withdrawal was the responsible course to take.

44. Denies each and every allegation contained in paragraph 44 of the Master Long Form Complaint and avers that the FDA approved VIOXX® as safe and effective for its intended uses subject to the information contained in its prescribing information and avers further that notwithstanding the voluntary withdrawal of VIOXX® on September 30, 2004 it would have been possible to continue to market VIOXX® with labeling that would incorporate the new data that led Merck to voluntarily withdraw VIOXX®, but given the availability of alternative therapies, and the questions raised by the data, Merck concluded that a voluntary withdrawal was the responsible course to take.

45. Denies each and every allegation contained in paragraph 45 of the Master Long Form Complaint.

46. Denies each and every allegation contained in paragraph 46 of the Master Long Form Complaint and avers that the FDA approved VIOXX® as safe and effective for its intended uses subject to the information contained in its prescribing information and avers further that notwithstanding the voluntary withdrawal of VIOXX® on September 30, 2004 it would have been possible to continue to market VIOXX® with labeling that would incorporate the new data that led Merck to voluntarily withdraw VIOXX®, but given the availability of alternative therapies, and the questions raised by the data, Merck concluded that a voluntary withdrawal was the responsible course to take.

47. Denies each and every allegation contained in paragraph 47 of the Master Long Form Complaint.

WHEREFORE, Merck respectfully demands judgment dismissing plaintiffs' Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

**RESPONSE TO "COUNT III NEW JERSEY CONSUMER
FRAUD ACT (N.J.S.A. 56:8-2 et seq.)"**

48. With respect to the allegations contained in paragraph 48 of the Master Long Form Complaint, repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 47 of this Answer with the same force and effect as though set forth here in full.

49. The allegations contained in paragraph 49 of the Master Long Form Complaint are legal conclusions as to which no responsive pleading is required. Should a

response be deemed required, Merck denies each and every allegation contained in said paragraph.

50. Denies each and every allegation contained in paragraph 50 of the Master Long Form Complaint, except admits that Merck manufactured, marketed, and distributed the prescription medicine VIOXX® until Merck voluntarily withdrew VIOXX® from the market on September 30, 2004.

51. Denies each and every allegation contained in paragraph 51 of the Master Long Form Complaint and avers that the FDA approved VIOXX® as safe and effective for its intended uses subject to the information contained in its prescribing information and avers further that notwithstanding the voluntary withdrawal of VIOXX® on September 30, 2004 it would have been possible to continue to market VIOXX® with labeling that would incorporate the new data that led Merck to voluntarily withdraw VIOXX®, but given the availability of alternative therapies, and the questions raised by the data, Merck concluded that a voluntary withdrawal was the responsible course to take.

52. Denies each and every allegation contained in paragraph 52 of the Master Long Form Complaint.

53. Denies each and every allegation contained in paragraph 53 of the Master Long Form Complaint.

54. Denies each and every allegation contained in paragraph 54 of the Master Long Form Complaint.

55. Denies each and every allegation contained in paragraph 55 of the Master Long Form Complaint, except to state that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations as to how Plaintiff was provided with VIOXX®

and by whom and why Plaintiff consumed VIOXX[®]. Should a further response be deemed required, Merck denies each and every allegation contained in said paragraph.

56. The allegations contained in paragraph 56 of the Master Long Form Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph.

57. Denies each and every allegation contained in paragraph 57 of the Master Long Form Complaint and avers that the FDA approved VIOXX[®] as safe and effective for its intended uses subject to the information contained in its prescribing information and avers further that notwithstanding the voluntary withdrawal of VIOXX[®] on September 30, 2004 it would have been possible to continue to market VIOXX[®] with labeling that would incorporate the new data that led Merck to voluntarily withdraw VIOXX[®], but given the availability of alternative therapies, and the questions raised by the data, Merck concluded that a voluntary withdrawal was the responsible course to take.

58. Denies each and every allegation contained in paragraph 58 of the Master Long Form Complaint.

59. Denies each and every allegation contained in paragraph 59 of the Master Long Form Complaint and avers that the FDA approved VIOXX[®] as safe and effective for its intended uses subject to the information contained in its prescribing information and avers further that notwithstanding the voluntary withdrawal of VIOXX[®] on September 30, 2004 it would have been possible to continue to market VIOXX[®] with labeling that would incorporate the new data that led Merck to voluntarily withdraw VIOXX[®], but given the availability of

alternative therapies, and the questions raised by the data, Merck concluded that a voluntary withdrawal was the responsible course to take.

60. Denies each and every allegation contained in paragraph 60 of the Master Long Form Complaint.

61. Denies each and every allegation contained in paragraph 61 of the Master Long Form Complaint.

62. The allegations contained in paragraph 62 of the Master Long Form Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph.

63. Denies each and every allegation contained in paragraph 63 of the Master Long Form Complaint.

64. Denies each and every allegation contained in paragraph 64 of the Master Long Form Complaint.

WHEREFORE, Merck respectfully demands judgment dismissing plaintiffs' Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

RESPONSE TO "COUNT IV BREACH OF EXPRESS WARRANTY"

65. With respect to the allegations contained in paragraph 65 of the Master Long Form Complaint, repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 64 of this Answer with the same force and effect as though set forth here in full.

66. Denies each and every allegation contained in paragraph 66 of the Master Long Form Complaint, except admits that Merck manufactured, marketed, and distributed the

prescription medicine VIOXX® until Merck voluntarily withdrew VIOXX® from the market on September 30, 2004.

67. Denies each and every allegation contained in paragraph 67 of the Master Long Form Complaint and avers that the FDA approved VIOXX® as safe and effective for its intended uses subject to the information contained in its prescribing information and avers further that notwithstanding the voluntary withdrawal of VIOXX® on September 30, 2004 it would have been possible to continue to market VIOXX® with labeling that would incorporate the new data that led Merck to voluntarily withdraw VIOXX®, but given the availability of alternative therapies, and the questions raised by the data, Merck concluded that a voluntary withdrawal was the responsible course to take.

68. Lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 68 of the Master Long Form Complaint. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph.

69. Denies each and every allegation contained in paragraph 69 of the Master Long Form Complaint.

70. The allegations contained in paragraph 70 of the Master Long Form Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph, and avers that the FDA approved VIOXX® as safe and effective for its intended uses subject to the information contained in its prescribing information and avers further that notwithstanding the voluntary withdrawal of VIOXX® on September 30, 2004 it would have been possible to continue to market VIOXX® with labeling that would incorporate the new data

that led Merck to voluntarily withdraw VIOXX®, but given the availability of alternative therapies, and the questions raised by the data, Merck concluded that a voluntary withdrawal was the responsible course to take. Merck further avers that it has not breached any duty under applicable law.

71. The allegations contained in paragraph 71 of the Master Long Form Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in paragraph 71 of the Master Long Form Complaint and avers that the FDA approved VIOXX® as safe and effective for its intended uses subject to the information contained in its prescribing information and avers further that notwithstanding the voluntary withdrawal of VIOXX® on September 30, 2004 it would have been possible to continue to market VIOXX® with labeling that would incorporate the new data that led Merck to voluntarily withdraw VIOXX®, but given the availability of alternative therapies, and the questions raised by the data, Merck concluded that a voluntary withdrawal was the responsible course to take.

72. Denies each and every allegation contained in paragraph 72 of the Master Long Form Complaint and avers that the FDA approved VIOXX® as safe and effective for its intended uses subject to the information contained in its prescribing information and avers further that notwithstanding the voluntary withdrawal of VIOXX® on September 30, 2004 it would have been possible to continue to market VIOXX® with labeling that would incorporate the new data that led Merck to voluntarily withdraw VIOXX®, but given the availability of alternative therapies, and the questions raised by the data, Merck concluded that a voluntary withdrawal was the responsible course to take.

73. Denies each and every allegation contained in paragraph 73 of the Master Long Form Complaint.

WHEREFORE, Merck respectfully demands judgment dismissing plaintiffs' Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

**RESPONSE TO "COUNT V PUNITIVE DAMAGES
UNDER THE PRODUCTS LIABILITY ACT (N.J.S.A.2A:58C-1)"**

74. With respect to the allegations contained in paragraph 74 of the Master Long Form Complaint, repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 73 of this Answer with the same force and effect as though set forth here in full.

75. Denies each and every allegation contained in paragraph 75 of the Master Long Form Complaint.

76. Denies each and every allegation contained in paragraph 76 of the Master Long Form Complaint.

77. Denies each and every allegation contained in paragraph 77 of the Master Long Form Complaint.

WHEREFORE, Merck respectfully demands judgment dismissing plaintiffs' Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

RESPONSE TO "COUNT VI WRONGFUL DEATH"

78. With respect to the allegations contained in paragraph 78 of the Master Long Form Complaint, repeats and realleges each and every admission, denial, averment, and

statement contained in paragraphs 1 through 77 of this Answer with the same force and effect as though set forth here in full.

79. Denies each and every allegation contained in paragraph 79 of the Master Long Form Complaint.

80. Denies each and every allegation contained in paragraph 80 of the Master Long Form Complaint.

81. Denies each and every allegation contained in paragraph 81 of the Master Long Form Complaint.

WHEREFORE, Merck respectfully demands judgment dismissing plaintiffs' Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

RESPONSE TO "COUNT VII SURVIVAL ACTION"

82. With respect to the allegations contained in paragraph 82 of the Master Long Form Complaint, repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 81 of this Answer with the same force and effect as though set forth here in full.

83. Denies each and every allegation contained in paragraph 83 of the Master Long Form Complaint.

84. Denies each and every allegation contained in paragraph 84 of the Master Long Form Complaint, except admits that Plaintiffs purport to state a claim for damages, but denies that there is any legal or factual basis for such relief.

WHEREFORE, Merck respectfully demands judgment dismissing plaintiffs' Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

RESPONSE TO "COUNT VIII LOSS OF CONSORTIUM"

85. With respect to the allegations contained in paragraph 85 of the Master Long Form Complaint, repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 84 of this Answer with the same force and effect as though set forth here in full.

86. Denies each and every allegation contained in paragraph 86 of the Master Long Form Complaint.

87. Denies each and every allegation contained in paragraph 87 of the Master Long Form Complaint.

WHEREFORE, Merck respectfully demands judgment dismissing plaintiffs' Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

**AS FOR A FIRST
DEFENSE, MERCK ALLEGES:**

88. Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

**AS FOR A SECOND
DEFENSE, MERCK ALLEGES:**

89. The Complaint fails to state a claim upon which relief can be granted.

**AS FOR A THIRD
DEFENSE, MERCK ALLEGES:**

90. Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver, or statutory and regulatory compliance.

**AS FOR A FOURTH
DEFENSE, MERCK ALLEGES:**

91. If plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

**AS FOR A FIFTH
DEFENSE, MERCK ALLEGES:**

92. Plaintiff is barred from recovering against Merck because plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by applicable federal law, including the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*

**AS FOR A SIXTH
DEFENSE, MERCK ALLEGES:**

93. To the extent to which plaintiffs assert claims based upon an alleged failure by Merck to warn plaintiffs directly of alleged dangers associated with the use of VIOXX®, such claims are barred because Merck has discharged its duty to warn under N.J.S.A. 2A:58C-4 in its warnings to the prescribing physician.

**AS FOR AN SEVENTH
DEFENSE, MERCK ALLEGES:**

94. If plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured plaintiffs.

**AS FOR AN EIGHTH
DEFENSE, MERCK ALLEGES:**

95. If plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were only so sustained after plaintiffs knowingly, voluntarily, and

willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any drug or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

**AS FOR A NINTH
DEFENSE, MERCK ALLEGES:**

96. If plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

**AS FOR TENTH
DEFENSE, MERCK ALLEGES:**

97. If plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by plaintiffs' misuse or abuse of VIOXX®.

**AS FOR AN ELEVENTH
DEFENSE, MERCK ALLEGES:**

98. If plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from plaintiffs' pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural course of conditions for which this defendant is not responsible.

**AS FOR A TWELFTH
DEFENSE, MERCK ALLEGES:**

99. Plaintiffs' claims are barred in whole or in part because VIOXX® is a prescription medication that is "unavoidably unsafe" within the meaning of comment k to Section 402A of the Restatement (Second) of Torts.

**AS FOR A THIRTEENTH
DEFENSE, MERCK ALLEGES:**

100. Plaintiffs' claims are barred in whole or in part because VIOXX® "provides net benefits for a class of patients" within the meaning of comment f to Section 6 of the Restatement (Third) of Torts: Product Liability.

**AS FOR A FOURTEENTH
DEFENSE, MERCK ALLEGES:**

101. To the extent that plaintiffs rely upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity and/or because the alleged warranties were disclaimed.

**AS FOR A FIFTEENTH
DEFENSE, MERCK ALLEGES:**

102. To the extent plaintiffs have settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

**AS FOR A SIXTEENTH
DEFENSE, MERCK ALLEGES:**

103. The product conformed to the state-of-the-art for the design and manufacture of such, or similar, product.

**AS FOR A SEVENTEENTH
DEFENSE, MERCK ALLEGES:**

104. To the extent plaintiffs are seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action under N.J.S.A. 2A:15-97.

**AS FOR AN EIGHTEENTH
DEFENSE, MERCK ALLEGES:**

105. Plaintiffs' claims are barred, in whole or in part, under the applicable state law because VIOXX® was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. §301.

**AS FOR A NINETEENTH
DEFENSE, MERCK ALLEGES:**

106. To the extent that plaintiffs seek punitive damages for the conduct that allegedly caused injuries asserted in the Complaint, such an award would also, if granted, violate Merck's state and federal constitutional rights.

**AS FOR A TWENTIETH
DEFENSE, MERCK ALLEGES:**

107. To the extent that plaintiffs seek punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless, or grossly negligent and, therefore, any award of punitive damages is barred.

**AS FOR A TWENTY-FIRST
DEFENSE, MERCK ALLEGES:**

108. Plaintiffs' demand for punitive damages is barred under N.J.S.A. 2A:58C-3 because VIOXX® was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. §301.

**AS FOR A TWENTY-SECOND
DEFENSE, MERCK ALLEGES:**

109. Plaintiffs' claims are barred in whole or in part by the First Amendment.

**AS FOR A TWENTY-THIRD
DEFENSE, MERCK ALLEGES:**

110. This defendant is not guilty of negligence and violated no duty owing to plaintiffs.

**AS FOR A TWENTY-FOURTH
DEFENSE, MERCK ALLEGES:**

111. Any liability that might otherwise be imposed upon this defendant is subject to reduction by the application of the doctrine of comparative negligence.

**AS FOR A TWENTY-FIFTH
DEFENSE, MERCK ALLEGES:**

112. Plaintiffs' claims are barred by their failure to prevent or mitigate the damages claimed.

**AS FOR A TWENTY-SIXTH
DEFENSE, MERCK ALLEGES:**

113. This defendant asserts all defenses available to it pursuant to N.J.S.A. 2A:58C-1, et seq., otherwise known as the New Jersey Product Liability Act.

**AS FOR A TWENTY-SEVENTH
DEFENSE, MERCK ALLEGES:**

114. Plaintiffs' claims are barred in whole or in part because Merck provided adequate "directions or warnings" as to the use of VIOXX® and any other Merck drug or pharmaceutical preparation plaintiffs allege to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

**AS FOR A TWENTY-EIGHTH
DEFENSE, MERCK ALLEGES:**

115. Plaintiffs' claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

**AS FOR A TWENTY-NINTH
DEFENSE, MERCK ALLEGES:**

116. This case is more appropriately brought in a different venue.

**AS FOR A THIRTIETH
DEFENSE, MERCK ALLEGES:**

117. Venue in this case is improper under R. 4:3-2.

**AS FOR A THIRTY-FIRST
DEFENSE, MERCK ALLEGES:**

118. This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

**AS FOR A THIRTY-SECOND
DEFENSE, MERCK ALLEGES:**

119. Plaintiffs' claims are barred, in whole or in part, because plaintiffs lack capacity and/or standing to bring such claims.

**AS FOR A THIRTY-THIRD
DEFENSE, MERCK ALLEGES:**

120. The extent of any risk associated with the use of Merck's product, the existence of which is not admitted, was, at the time of the distribution of the product by Merck, unknown and could not have been known by the use of ordinary care by Merck.

**AS FOR A THIRTY-FOURTH
DEFENSE, MERCK ALLEGES:**

121. Each and every claim asserted or raised in the Complaint is barred by the doctrines of accord and satisfaction, res judicata, payment and release.

**AS FOR A THIRTY-FIFTH
DEFENSE, MERCK ALLEGES:**

Plaintiff's damages are barred or reduced by the doctrine of avoidable consequences.

**AS FOR A THIRTY-SIXTH
DEFENSE, MERCK ALLEGES:**

To the extent plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to Buckman Co. v. Plaintiff's Legal Committee, 531 U.S. 341 (2001).

**AS FOR A THIRTY-SEVENTH
DEFENSE, MERCK ALLEGES:**

Plaintiff's claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction; the FDA is charged under the law with regulating prescription drugs, including VIOXX®, and is specifically charged with determining the content of warnings and labeling for prescription drugs.

**AS FOR A THIRTY-EIGHTH
DEFENSE, MERCK ALLEGES:**

Plaintiff's claims are barred pursuant to the Learned Intermediary Doctrine.

**AS FOR A THIRTY-NINTH
DEFENSE, MERCK ALLEGES:**

Plaintiff's purported allegations of misrepresentation and fraud have not been plead with particularity.

**AS FOR A FORTIETH
DEFENSE, MERCK ALLEGES:**

There is no causal relationship between Merck or its activities described in the Complaint and any injuries or damages allegedly sustained by plaintiff.

**AS FOR A FOURTY-FIRST
DEFENSE, MERCK ALLEGES:**

Merck states that the benefits of VIOXX® outweigh the risks, if any, which may be attendant to its use in appropriate person in accordance with the prescribing information.

**AS FOR A FOURTY-SECOND
DEFENSE, MERCK ALLEGES:**

Merck denies that it is jointly or severally liable with any other defendant for damages, if any, to plaintiff.

**AS FOR A FOURTY-THIRD
DEFENSE, MERCK ALLEGES:**

With respect to plaintiff's demand for punitive damages, Merck specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards which arose in the decisions of BMW of North America v. Gore, 116 U.S. 1589 (1996), Cooper Industries, Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424 (2001), and State Farm Mut. Auto. Ins. Co. v. Campbell, 123 S.Ct. 1513 (U.S. 2003).

**AS FOR A FOURTY-FOURTH
DEFENSE, MERCK ALLEGES:**

To the extent that plaintiff attempts to seek equitable relief, plaintiff is not entitled to such relief because plaintiff has an adequate remedy at law.

**AS FOR A FOURTY-FIFTH
DEFENSE, MERCK ALLEGES:**

Plaintiff is barred from recovery and/or plaintiff's recovery is limited pursuant to the Comparative Negligence Act, N.J.S.A. 2A:15-5.1, et seq.

**AS FOR A FOURTY-SIXTH
DEFENSE, MERCK ALLEGES:**

Merck denies any liability on its part, but if Merck is ultimately found liable to plaintiff, then it shall only be liable for its equitable share of plaintiff's recovery since any liability which would be found against it will be insufficient to impose joint liability. In the

alternative, the liability, if any, of Merck is limited by and pursuant to the New Jersey Joint Tortfeasor Contribution Act, N.J.S.A. 2A:53A-1, et seq.

WHEREFORE, Merck respectfully demands judgment dismissing plaintiffs' Complaint with prejudice and awarding Merck its reasonable attorney's fees, together with such other and further relief that the Court may deem just and proper.

JURY DEMAND

The defendant, Merck, hereby demands a trial by jury of twelve (12) on all issues so triable.

DEMAND FOR STATEMENT OF DAMAGES

PLEASE TAKE NOTICE that pursuant to R. 4:5-2, defendant Merck demands that plaintiffs furnish a statement of damages claimed within the time prescribed by the Rules of Court.

CERTIFICATION PURSUANT TO RULE 4:5-1

I certify that I am not aware of the matter in controversy being the subject of any other action pending in any court or arbitration forum. I certify that no such action or arbitration proceeding is presently contemplated.

CERTIFICATION

I certify that a copy of the within Answer was served within the time prescribed

by R. 4:6-1.

Dated:

HUGHES HUBBARD & REED LLP
A New York Limited Liability Partnership
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Merck & Co., Inc.

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