

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

NATIONAL ASSOCIATION OF CHAIN)	
DRUG STORES <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	Civil Action No. 1:07cv02017 (RCL)
v.)	
)	
UNITED STATES DEPARTMENT OF)	
HEALTH AND HUMAN SERVICES <i>et al.</i> ,)	
)	
Defendants.)	

DEFENDANTS’ ANSWER TO PLAINTIFFS’ SECOND AMENDED COMPLAINT

The U.S. Department of Health and Human Services (“HHS”), Michael O. Leavitt, Secretary of HHS, the Centers for Medicare & Medicaid Services (“CMS”), and Kerry Weems, Acting Administrator of CMS (collectively, “Defendants”), assert the following defenses to all causes of action asserted against them in Plaintiffs’ Second Amended Complaint, without assuming the burden of proof on any issue as to which the burden would otherwise rest on Plaintiffs, and reserve the right to assert any other defense that may become available or appear during the proceedings in this case:

FIRST DEFENSE

Plaintiffs’ claims are barred in whole or in part because this Court lacks subject matter jurisdiction.

SECOND DEFENSE

Plaintiffs’ claims are barred in part because they are moot.

THIRD DEFENSE

Plaintiffs have failed to state a claim on which relief can be granted.

FOURTH DEFENSE

The challenged regulations are consistent with the governing statute and were promulgated in accordance with law.

FIFTH DEFENSE

Defendants answer the numbered paragraphs of the Second Amended Complaint as follows:

1. Defendants admit that Plaintiffs' Second Amended Complaint purports to challenge the "average manufacturer price rule" ("AMP rule"), a final rule implementing certain Medicaid-related provisions of the Deficit Reduction Act of 2005 ("DRA") as well as various other aspects of the Medicaid program. Paragraph 1 in all other respects states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 1.

2. Paragraph 2 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 2.

3. Defendants admit that CMS's Office of the Actuary has estimated that the DRA is likely to result in Medicaid savings of \$21 billion from 2007 through 2016; admit the existence of the cited reports of the HHS Office of Inspector General ("OIG") and the Government Accountability Office ("GAO"), to which the Court is referred for a full and accurate statement of their contents; and deny the remaining allegations in Paragraph 3.

4. Defendants admit that the billions of dollars the federal and state governments were projected to save as a result of the DRA were expected to be realized largely through lower payments to pharmacies, 72 Fed. Reg. 39,142, 39,233 (July 17, 2007), who have until now received artificially inflated payments for certain prescription drugs dispensed to Medicaid

beneficiaries. The second and third sentences of Paragraph 4 state legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in the second and third sentences of Paragraph 4. Defendants deny the remaining allegations in Paragraph 4.

5. Defendants admit that Plaintiffs' Second Amended Complaint seeks to enjoin Defendants from implementing the AMP rule and from posting AMP data on a public website as the DRA requires. Defendants further admit that Plaintiffs' Second Amended Complaint seeks a declaratory judgment that the AMP rule is unlawful. Defendants deny the remaining allegations in Paragraph 5.

6. Paragraph 6 purports to summarize a written ruling of this Court, which speaks for itself. To the extent a response is required, Defendants admit the allegations in Paragraph 6, and further refer the Court to the cited ruling for a full and accurate statement of its contents.

7. Defendants admit the allegations in Paragraph 7.

8. Paragraph 8 purports to summarize a regulation, which speaks for itself. Defendants admit that on March 14, 2008, CMS issued an interim final rule with comment period – which, but for the injunction entered in this case, would have become effective on April 14, 2008 – amending the regulatory definition of “multiple source drug” (“interim MSD rule”), and further refer the Court to the cited regulation for a full and accurate statement of its contents. Defendants deny the remaining allegations in Paragraph 8.

9. Paragraph 9 purports to summarize *Federal Register* notices, which speak for themselves. Defendants admit the existence of the cited *Federal Register* notices, to which the Court is referred for a full and accurate statement of their contents; admit that the interim MSD rule was issued as an “interim final rule with comment period,” 73 Fed. Reg. 13,785 (Mar. 14,

2008); admit that comments regarding the interim MSD rule were due on April 14, 2008, *id.* at 13,785; admit that, but for the injunction entered in this case, the interim MSD rule would have become effective on April 14, 2008, *id.*; admit that CMS stated in the preamble to the interim MSD rule that, because it was changing the regulatory definition of the term “multiple source drug” to reflect the statutory definition of that term, “[w]e would not be able to change the definition in this regulation in response to public comment,” *id.* at 13,787; admit that CMS received 9 comments during the open comment period for the MSD rule, 73 Fed. Reg. 58,491, 58,492 (Oct. 7, 2008); admit that CMS received over 1,600 comments during the open comment period for the AMP rule, 72 Fed. Reg. at 39,157; and deny the remaining allegations in Paragraph 9.

10. Paragraph 10 purports to summarize a regulation, which speaks for itself. Defendants admit the existence of the cited regulation, to which the Court is referred for a full and accurate statement of its contents; admit that CMS finalized the MSD rule on October 7, 2008; and admit that the final MSD rule revised one subparagraph of the interim MSD rule. 73 Fed. Reg. at 58,491-97. Defendants deny the remaining allegations in Paragraph 10.

11. Defendants admit that Plaintiffs’ Second Amended Complaint purports to challenge the MSD rule. Paragraph 11 in all other respects states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 11.

12. Defendants admit that Plaintiffs’ Second Amended Complaint seeks to enjoin Defendants from implementing the MSD rule. Defendants further admit that Plaintiffs’ Second Amended Complaint seeks a declaratory judgment that the MSD rule fails to comply with the

Social Security Act and the Administrative Procedure Act. Defendants deny the remaining allegations in Paragraph 12.

13. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 13, and the allegations are therefore denied.

14. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 14, and the allegations are therefore denied.

15. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 15, and the allegations are therefore denied.

16. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in the first and second sentences of Paragraph 16, and the allegations are therefore denied. Defendants admit that, prior to the injunction entered by this Court on December 19, 2007, CMS had intended to set federal upper reimbursement limits (“FULs”) for Medicaid-covered multiple source prescription drugs based on AMPs calculated pursuant to the challenged rule, as the DRA required, and that these FULs would apply to drugs dispensed in 2008. Defendants deny the remaining allegations in Paragraph 16.

17. Paragraph 17 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 17.

18. Defendants admit the allegations in Paragraph 18.

19. Defendants admit that Plaintiffs’ Second Amended Complaint purports to sue Defendant Leavitt solely in his official capacity as Secretary of HHS.

20. Defendants admit the allegations in Paragraph 20.

21. Defendants admit that Plaintiffs’ Second Amended Complaint purports to sue Defendant Weems solely in his official capacity as Acting Administrator of CMS.

22. Paragraph 22 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 22.

23. Paragraph 23 states legal conclusions to which no response is required. To the extent a response is required, Defendants admit that venue in this District is proper under 28 U.S.C. § 1391.

24. Defendants admit the allegations in the first sentence of Paragraph 24. Defendants further admit that, to the extent a state has chosen to participate in the Medicaid program, the federal and state governments jointly fund the Medicaid program in that state, that the program is administered by each participating state in accordance with a Medicaid State Plan that is reviewed and approved by CMS, and that each participating state must comply with applicable federal requirements set forth in the Social Security Act, CMS regulations, and CMS program guidance. Defendants deny the remaining allegations in Paragraph 24.

25. Defendants admit that retail pharmacies may choose to dispense covered prescription drugs to Medicaid beneficiaries and that, if they do so, those pharmacies are paid for those drugs by their state's Medicaid program. Defendants further admit that state payments to pharmacies vary depending on the payment methodology set forth in the applicable State Plan. Defendants further admit that "single source drugs" are commonly referred to as "brand name drugs" and that "multiple sources drugs" are commonly referred to as "generic drugs." Defendants deny the remaining allegations in Paragraph 25.

26. Paragraph 26 purports to summarize a statutory provision, which speaks for itself, and states legal conclusions to which no response is required. To the extent a response is required, Defendants admit the existence of the cited statutory provision, to which the Court is referred for a full and accurate statement of its contents; admit that the Social Security Act

requires Defendants to set FULs for Medicaid-covered multiple source prescription drugs, 42 U.S.C. § 1396r-8(e)(4); admit that State Plans must provide assurance that the state's aggregate Medicaid expenditures for multiple source drugs are below the aggregate FULs for those drugs, 42 C.F.R. § 447.518(b)(1)(i); and deny the remaining allegations in Paragraph 26.

27. Paragraph 27 purports to summarize a statutory provision, which speaks for itself, and states legal conclusions to which no response is required. To the extent a response is required, Defendants admit the existence of the cited statute, to which the Court is referred for a full and accurate statement of its contents; admit that, under the Omnibus Budget Reconciliation Act of 1990 ("OBRA"), drug manufacturers pay rebates to states to the extent that their drugs are distributed to Medicaid beneficiaries, Pub. L. No. 101-508, 104 Stat. 1388, § 4401 (1990), *codified at* 42 U.S.C. § 1396r-8; admit that the amount of these rebates is based, in part, on the drug's AMP, which is defined, in part, as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade," 42 U.S.C. §§ 1396r-8(c), (k)(1); admit that participating manufacturers calculate AMPs for their drugs and periodically report those AMPs to CMS, *id.* § 1396r-8(b)(3)(A); and deny the remaining allegations in Paragraph 27.

28. Paragraph 28 purports to summarize statutory provisions, which speak for themselves, and states legal conclusions to which no response is required. To the extent a response is required, Defendants admit the existence of the cited statutory provisions, to which the Court is referred for a full and accurate statement of their contents; admit that the DRA amended the Social Security Act to require CMS to set FULs for multiple source drugs based on the AMP of the least costly therapeutic equivalent, *see* Pub. L. No. 109-171, 120 Stat. 4, 55, § 6001(a)(2) (2006), *codified at* 42 U.S.C. § 1396r-8(e)(5); admit that the Social Security Act

defines “AMP” and “multiple source drug,” 42 U.S.C. §§ 1396r-8(k)(1), (7)(A)(i); and deny the remaining allegations in Paragraph 28.

29. Paragraph 29 purports to summarize regulatory provisions, which speak for themselves, and states legal conclusions to which no response is required. To the extent a response is required, Defendants admit the existence of the cited regulation, to which the Court is referred for a full and accurate statement of its contents; admit that CMS promulgated the AMP rule on July 17, 2007, pursuant to an explicit directive from Congress in the DRA, § 6001(c)(3)(B); admit that under the DRA CMS must set FULs for multiple sources drugs at 250 percent of the AMP of the least costly therapeutic equivalent, *id.* § 6001(a)(2), *codified at* 42 U.S.C. § 1396r-8(e)(5); *see also* 42 C.F.R. § 447.514(b); and deny the remaining allegations in Paragraph 29.

30. Paragraph 30 purports to summarize a statutory provision, which speaks for itself, and states legal conclusions to which no response is required. To the extent a response is required, Defendants admit the existence of the cited statutory provision, to which the Court is referred for a full and accurate statement of its contents; admit that AMP is defined, in part, as “the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade,” 42 U.S.C. § 1396r-8(k)(1); and deny the remaining allegations in Paragraph 30.

31. Paragraph 31 purports to summarize a statutory provision, which speaks for itself, and states legal conclusions to which no response is required. To the extent a response is required, Defendants admit that the Social Security Act defines AMP, in part, as follows: “with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the

retail pharmacy class of trade,” *id.* § 1396r-8(k)(1); and deny the remaining allegations in Paragraph 31.

32. Paragraph 32 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 32.

33. Paragraph 33 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 33.

34. Paragraph 34 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 34.

35. Paragraph 35 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 35.

36. Paragraph 36 purports to summarize a regulatory provision, which speaks for itself, and states legal conclusions to which no response is required. To the extent a response is required, Defendants admit the existence of the cited regulatory provision, to which the Court is referred for a full and accurate statement of its contents, and deny the remaining allegations in Paragraph 36.

37. Paragraph 37 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 37.

38. Paragraph 38 purports to summarize statutory and regulatory provisions, which speak for themselves, and states legal conclusions to which no response is required. To the extent a response is required, Defendants admit the existence of the cited statutory and regulatory provisions, to which the Court is referred for a full and accurate statement of their contents, and deny the remaining allegations in Paragraph 38.

39. Defendants admit that the same prices may not be available to all entities that purchase prescription drugs from manufacturers and that some entities may, in certain circumstances, pay less or more than Plaintiffs' members for some prescription drugs. Defendants deny the remaining allegations in the first and third sentences of Paragraph 39. The second and fourth sentences of Paragraph 39 purport to summarize federal and state laws, which speak for themselves, and state legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in the second and fourth sentences of Paragraph 39.

40. Defendants admit that, with respect to multiple source drugs, lower AMPs generally lead to lower rebates. *See* 42 U.S.C. § 1396r-8(c)(3)(A). Paragraph 40 in all other respects purports to summarize statutory and regulatory provisions, which speak for themselves, and states legal conclusions to which no response is required. To the extent a response is required, Defendants admit the existence of the cited regulatory provision, to which the Court is referred for a full and accurate statement of its contents, and deny the remaining allegations in Paragraph 40.

41. Defendants admit that they are required, under the DRA, to post AMP data to a public website, *id.* § 1396r-8(b)(3)(D)(v); admit that CMS has stated that, "[w]hile there is no requirement that States use AMPs to set payment amounts, . . . Congress intended that States have drug pricing data based on actual prices, in contrast to previously available data that did not necessarily reflect actual manufacturer prices of sales to the retail pharmacy class of trade," 72 Fed. Reg. at 39,146; and deny the remaining allegations in Paragraph 41.

42. Paragraph 42 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 42.

43. Paragraph 43 purports to summarize regulatory provisions, which speak for themselves. To the extent a response is required, Defendants admit the existence of the cited regulatory provisions, to which the Court is referred for a full and accurate statement of their contents; admit that the AMP rule establishes the methodology for calculating AMPs and that, under the DRA, CMS must set FULs for certain drugs based on the AMP, 42 U.S.C. §§ 1396r-8(e)(4), (5); and deny the remaining allegations in Paragraph 43.

44. Paragraph 44 purports to summarize a statutory provision, which speaks for itself, and states legal conclusions to which no response is required. To the extent a response is required, Defendants admit the existence of the cited statutory provision, to which the Court is referred for a full and accurate statement of its contents; admit that CMS must establish a FUL for every multiple source drug, *id.* § 1396r-8(e)(4); and deny the remaining allegations in Paragraph 44.

45. Paragraph 45 purports to summarize a statutory provision, which speaks for itself, and states legal conclusions to which no response is required. To the extent a response is required, Defendants admit the existence of the cited statutory provision, to which the Court is referred for a full and accurate statement of its contents; deny the allegations in the first and second sentences of Paragraph 45 except to admit that a drug is a “multiple source drug” under the Social Security Act if at least two equivalent drug products are “sold or marketed in the State during the period,” *id.* § 1396r-8(k)(7)(A)(i); and admit the allegations in the third sentence of Paragraph 45.

46. Paragraph 46 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 46.

47. The first sentence of Paragraph 47 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in the first sentence of Paragraph 47. Defendants admit that “in light of the DRA amendments, CMS will not be using the published compendia of cost information (e.g., *Red Book*, *First DataBank*, or *Medi-Span*) to establish and set the FUL,” 72 Fed. Reg. at 39,216, and deny the remaining allegations in the second sentence of Paragraph 47.

48. Paragraph 48 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 48.

49. Defendants admit that the MSD rule amended the AMP rule’s definition of “multiple source drug” and that the amended definition of “multiple source drug” reflects the statutory definition of “multiple source drug.” *See* 42 U.S.C. § 1396r-8(k)(7). The remaining allegations in Paragraph 49 state legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 49.

50. Paragraph 50 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 50.

51. Paragraph 51 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 51.

52. Paragraph 52 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 52.

53. Paragraph 53 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 53.

54. Defendants deny the allegations in Paragraph 54.

55. Paragraph 55 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 55.

56. Paragraph 56 purports to summarize a statutory provision, which speaks for itself, and states legal conclusions to which no response is required. To the extent a response is required, Defendants admit the allegations in Paragraph 56, and further refer the Court to the cited statutory provision for a full and accurate statement of its contents.

57. Paragraph 57 purports to summarize a statutory provision, which speaks for itself, and states legal conclusions to which no response is required. To the extent a response is required, Defendants admit the allegations in Paragraph 57, and further refer the Court to the cited statutory provision for a full and accurate statement of its contents.

58. The first sentence of Paragraph 58 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in the first sentence of Paragraph 58. Defendants admit that they have long applied FULs to B-rated drugs, *see* 72 Fed. Reg. at 39,155, and deny the remaining allegations in the second sentence of Paragraph 58. Defendants deny the allegations in the third sentence of Paragraph 58.

59. Paragraph 59 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 59.

60. Defendants deny the allegations in Paragraph 60.

61. Defendants incorporate each of their previous responses corresponding to Paragraphs 1 through 60 of the Second Amended Complaint, as if fully set forth herein.

62. Paragraph 62 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 62.

63. Paragraph 63 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 63.

64. Defendants incorporate each of their previous responses corresponding to Paragraphs 1 through 63 of the Second Amended Complaint, as if fully set forth herein.

65. Paragraph 65 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 65.

66. Paragraph 66 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 66.

67. Defendants incorporate each of their previous responses corresponding to Paragraphs 1 through 66 of the Second Amended Complaint, as if fully set forth herein.

68. Paragraph 68 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 68.

69. Paragraph 69 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 69.

70. Defendants incorporate each of their previous responses corresponding to Paragraphs 1 through 69 of the Second Amended Complaint, as if fully set forth herein.

71. Defendants admit that the interim MSD rule was issued as an interim final rule with comment period; admit that comments on the interim MSD rule were due on April 14, 2008; admit that, but for the injunction entered in this case, the rule would have become effective on April 14, 2008; and deny the remaining allegations in Paragraph 71.

72. Paragraph 72 purports to summarize a *Federal Register* notice, which speaks for itself. Defendants admit the existence of the cited *Federal Register* notice, to which the Court is referred for a full and accurate statement of its contents; admit that CMS did not issue a notice of

proposed rulemaking prior to issuing the interim MSD rule; admit that CMS did not consider or respond to public comments in the interim MSD rule but did consider and respond to public comments in the final MSD rule; admit that the interim MSD rule was “not being issued in response to public comments received on the July 2007 AMP final rule with comment period,” 73 Fed. Reg. at 13,786; and deny the remaining allegations in Paragraph 72.

73. Paragraph 73 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 73.

74. Paragraph 74 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 74.

75. Defendants incorporate each of their previous responses corresponding to Paragraphs 1 through 74 of the Second Amended Complaint, as if fully set forth herein.

76. Paragraph 76 purports to summarize a statutory provision, which speaks for itself, and states legal conclusions to which no response is required. To the extent a response is required, Defendants admit the existence of the cited statutory provision, to which the Court is referred for a full and accurate statement of its contents, and deny the remaining allegations in Paragraph 76.

77. Paragraph 77 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 77.

78. Paragraph 78 purports to summarize a *Federal Register* notice, which speaks for itself, and states legal conclusions to which no response is required. To the extent a response is required, Defendants admit the existence of the cited *Federal Register* notice, to which the Court is referred for a full and accurate statement of its contents, and deny the remaining allegations in Paragraph 78.

79. Paragraph 79 purports to summarize a *Federal Register* notice, which speaks for itself, and states legal conclusions to which no response is required. To the extent a response is required, Defendants admit the existence of the cited *Federal Register* notice, to which the Court is referred for a full and accurate statement of its contents, and deny the remaining allegations in Paragraph 79.

80. Paragraph 80 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 80.

81. Defendants incorporate each of their previous responses corresponding to Paragraphs 1 through 80 of the Second Amended Complaint, as if fully set forth herein.

82. The first and third sentences of Paragraph 82 state legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in the first and third sentences of Paragraph 82. The fourth and seventh sentences of Paragraph 82 purport to summarize *Federal Register* notices, which speak for themselves. Defendants admit the existence of the cited *Federal Register* notices, to which the Court is referred for a full and accurate statement of their contents; admit that the interim MSD rule called for public comment; admit that Defendants stated in the interim MSD rule that “[w]e would not be able to change the definition in this regulation in response to public comment,” 73 Fed. Reg. at 13,787; admit that the final MSD rule made two corrections to the regulatory definition of the statutory term “multiple source drug” in order to mirror the statutory definition, 73 Fed. Reg. at 58,496; admit that Defendants received 9 comments in response to the interim MSD rule, *id.* at 58,492; and deny the remaining allegations in Paragraph 82.

83. The first sentence of Paragraph 83 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in the first

sentence of Paragraph 83. Defendants admit that CMS received comments regarding a prior definition of the term “multiple source drug” during the open comment period associated with the AMP rule; admit that CMS, in promulgating the final MSD rule, did not consider or address public comments other than those it received in response to the revised definition of the term “multiple source drug” contained in the interim MSD rule; and deny the remaining allegations in Paragraph 83.

84. Paragraph 84 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 84.

85. Paragraph 85 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 85.

86. Defendants incorporate each of their previous responses corresponding to Paragraphs 1 through 85 of the Second Amended Complaint, as if fully set forth herein.

87. Paragraph 87 purports to summarize a statutory provision, which speaks for itself, and states legal conclusions to which no response is required. To the extent a response is required, Defendants admit the existence of the cited statutory provision, to which the Court is referred for a full and accurate statement of its contents, and deny the remaining allegations in Paragraph 87.

88. Paragraph 88 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 88.

89. Paragraph 89 purports to summarize a *Federal Register* notice, which speaks for itself, and states legal conclusions to which no response is required. To the extent a response is required, Defendants admit the existence of the cited *Federal Register* notice, to which the Court

is referred for a full and accurate statement of its contents, and deny the remaining allegations in Paragraph 89.

90. Paragraph 90 purports to summarize a *Federal Register* notice, which speaks for itself, and states legal conclusions to which no response is required. To the extent a response is required, Defendants admit the existence of the *Federal Register* notice, to which the Court is referred for a full and accurate statement of its contents, and deny the remaining allegations in Paragraph 90.

91. Paragraph 91 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 91.

92. Defendants deny the allegations in Paragraph 92.

93. Paragraph 93 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 93.

ADDITIONAL DENIAL

Defendants deny each and every allegation of the Second Amended Complaint, including each and every request for relief, not specifically admitted in this Answer.

DEFENDANTS' PRAYER FOR RELIEF

WHEREFORE, Defendants respectfully request that the Court dismiss Plaintiffs' Second Amended Complaint with prejudice and award such further relief as the Court may deem just and proper.

Respectfully submitted,

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s/ Wendy M. Ertmer

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Dated: November 24, 2008

Counsel for Defendants

CERTIFICATE OF SERVICE

I hereby certify that on November 24, 2008, a copy of the foregoing pleading was filed electronically via the Court's ECF system, through which a notice of the filing will be sent to

Frederick R. Ball	frball@duanemorris.com
Nicholas J. Lynn	njlynn@duanemorris.com
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and was sent by electronic mail to:

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s/ Wendy M. Ertmer

WENDY M. ERTMER