

**UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

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NATURAL RESOURCES DEFENSE	)	)	
COUNCIL, et al.,	)	)	
	)	)	
Plaintiffs,	)	ANSWER	
	)	)	
v.	)	11 CIV 3562 (RMB)	
	)	ECF CASE	
UNITED STATES FOOD AND DRUG	)		
ADMINISTRATION, <i>et al.</i> ,	)		
	)		
Defendants.	)		
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Defendants, the United States Food and Drug Administration, Margaret Hamburg, in her official capacity as Commissioner, United States Food and Drug Administration (“FDA”); Center for Veterinary Medicine; Bernadette Dunham, in her official capacity as Director, Center for Veterinary Medicine; United States Department of Health and Human Services; and Kathleen Sebelius, in her official capacity as Secretary, United States Department of Health and Human Services (collectively, “Defendants”), by their attorney, Preet Bharara, United States Attorney for the Southern District of New York, answer the first amended complaint (the “Amended Complaint”) of plaintiffs Natural Resources Defense Council, Inc., Center for Science in the Public Interest, Food Animal Concerns Trust, Public Citizen, Inc., and Union of Concerned Scientists, Inc. (collectively, “Plaintiffs”) upon information and belief as follows:

1. Defendants admit that the misuse and overuse of certain antibiotics can result in antimicrobial resistance that is harmful to human health and otherwise deny the allegations contained in the first two sentences of paragraph 1 of the Amended Complaint. Defendants admit that the final sentence of this paragraph contains a statement made by the Institute of Medicine of the National Academy of Sciences.

2. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in the first and third sentences of paragraph 2 of the Amended Complaint, as those allegations are vague due to Plaintiffs' use of undefined terminology such as "approximately," and "cramped." Defendants deny the allegations contained in the second sentence of paragraph 2 of the Amended Complaint and admit the allegations contained in the final sentence of this paragraph.

3. Defendants admit that the FDA is one of the governmental entities that regulate the use of antibiotics in livestock and otherwise deny the allegations contained in the first sentence of paragraph 3 of the Amended Complaint. Defendants admit that, since the 1950s, FDA has approved some antibiotics for disease prevention in animals, and has approved some antibiotics for purposes of growth promotion, and otherwise deny the allegations contained in the second sentence of paragraph 3 of the Amended Complaint. Defendants admit that the approved dose of an antibiotic for growth promotion is typically less than the approved dose for a disease indication, and otherwise deny the allegations contained in the third sentence of paragraph 3 of the Amended Complaint. Defendants admit that some of the antibiotics that were originally approved for disease prevention and growth promotion indications may be important in human medicine, and otherwise deny the allegations contained in the final sentence of paragraph 3 of the Amended Complaint.

4. The first sentence of paragraph 4 of the Amended Complaint states the legal opinion and conclusions of Plaintiffs as to which no answer is required. To the extent that an answer to this sentence is required, Defendants admit that the first sentence of paragraph 4 of the Amended Complaint purports to describe a provision contained in the Federal Food, Drug, and Cosmetic Act ("FFDCA"), and respectfully refer the Court to the cited statutory provision for a

full and complete statement of its contents. Defendants deny the remainder of the allegations contained in paragraph 4 of the Amended Complaint other than to admit that FDA has not withdrawn approvals for penicillin and tetracycline as proposed in the 1977 notices of opportunity for hearings (the “NOOHs”).

5. Defendants deny the allegations contained in paragraph 5 of the Amended Complaint.

6. Defendants admit that in 1999 and 2005, certain of the Plaintiffs submitted citizen petitions (the “Citizen Petitions”) to FDA and that the first sentence of paragraph 6 of the Amended Complaint purports to characterize those Citizen Petitions. Defendants admit the allegations contained in the second sentence of paragraph 6 of the Amended Complaint.

7. Defendants deny the allegations contained in paragraph 7 of the Amended Complaint.

8. Paragraph 8 of the Amended Complaint consists of Plaintiffs’ characterization of the Amended Complaint, as to which no answer is required. To the extent that an answer to this paragraph is required, Defendants admit that Plaintiffs purport to seek the requested relief, but deny that they are entitled to it.

9. Paragraph 9 of the Amended Complaint states the legal opinions and conclusions of the Plaintiffs, including citations to legal authority and a statement as to the purported jurisdiction of this Court, as to which no answer is required. To the extent that this paragraph contains factual allegations that may require an answer, the Defendants deny all such allegations.

10. Paragraph 10 of the Amended Complaint states the legal opinions and conclusions of the Plaintiffs, including citations to legal authority and a statement as to the purported jurisdiction of this Court, as to which no answer is required. To the extent that this paragraph

contains factual allegations that may require an answer, Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of such allegations.

11. Paragraph 11 of the Amended Complaint states the legal opinions and conclusions of the Plaintiffs, including citations to legal authority, as to which no answer is required. To the extent that this paragraph contains factual allegations that may require an answer, Defendants deny all such allegations.

12. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 12 of the Amended Complaint.

13. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 13 of the Amended Complaint.

14. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 14 of the Amended Complaint.

15. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 15 of the Amended Complaint.

16. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 16 of the Amended Complaint.

17. Paragraph 17 of the Amended Complaint states the legal opinions and conclusions of the Plaintiffs, including a statement regarding their purported standing to serve as plaintiffs in this action, as to which no answer is required. To the extent that this paragraph contains factual allegations that may require an answer, Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of such allegations.

18. Defendants admit the allegations contained in the first sentence of paragraph 18 of the Amended Complaint, and deny the allegations contained in the remaining sentences of this paragraph.

19. Paragraph 19 of the Amended Complaint states the legal opinions and conclusions of the Plaintiffs, as to which no answer is required. To the extent that an answer to this paragraph is required, Defendants admit that Dr. Hamburg is an officer of the United States acting in her official capacity and that the FFDCa contains provisions regarding the withdrawal of approval for new animal drugs for safety-related reasons, and otherwise deny these allegations.

20. Paragraph 20 of the Amended Complaint states the legal opinions and conclusions of the Plaintiffs, as to which no answer is required. To the extent that an answer to this paragraph is required, Defendants admit that the Administrative Procedure Act contains standards for FDA's response to properly submitted Citizen Petitions.

21. Paragraph 21 of the Amended Complaint states the legal opinions and conclusions of the Plaintiffs, as to which no answer is required. To the extent that an answer to this paragraph is required, Defendants admit that Dr. Dunham is an officer of the United States acting in her official capacity, and that she has been delegated certain responsibilities with respect to the approval and withdrawal of new animal drugs, and otherwise deny these allegations.

22. Paragraph 22 of the Amended Complaint states the legal opinions and conclusions of the Plaintiffs, as to which no answer is required. To the extent that an answer to this paragraph is required, Defendants admit that Secretary Sebelius is an officer of the United States acting in her official capacity, and that she has certain responsibilities with respect to the

approval and withdrawal of new animal drugs, most of which have been lawfully delegated to FDA, and otherwise deny these allegations.

23. Paragraph 23 of the Amended Complaint contains no allegations.

24. Paragraph 24 of the Amended Complaint states the legal opinion and conclusions of Plaintiffs, including a citation to legal authority, as to which no answer is required. To the extent that an answer to these allegations is required, Defendants admit that this paragraph purports to describe provisions contained in the FFDCA and respectfully refer the Court to the cited statutory provisions for a full and complete statement of their contents.

25. Paragraph 25 of the Amended Complaint states the legal opinion and conclusions of Plaintiffs, including a citation to legal authority, as to which no answer is required. To the extent that an answer to these allegations is required, Defendants admit that this paragraph purports to describe a provision contained in the FFDCA and respectfully refer the Court to the cited statutory provision for a full and complete statement of its contents.

26. Paragraph 26 of the Amended Complaint states the legal opinion and conclusions of Plaintiffs, including a citation to legal authority, as to which no answer is required. To the extent that an answer to these allegations is required, Defendants admit that this paragraph purports to describe provisions contained in the FFDCA and associated staff manual guides, and respectfully refer the Court to the cited statutory provisions and staff manual guides for a full and complete statement of their contents.

27. Paragraph 27 of the Amended Complaint states the legal opinion and conclusions of Plaintiffs, including a citation to legal authority, as to which no answer is required. To the extent that an answer to these allegations is required, Defendants admit that this paragraph

purports to describe a provision contained in regulations promulgated by FDA, and respectfully refer the Court to the cited regulatory provision for a full and complete statement of its contents.

28. Paragraph 28 of the Amended Complaint states the legal opinion and conclusions of Plaintiffs, including a citation to legal authority, as to which no answer is required. To the extent that an answer to these allegations is required, Defendants admit that this paragraph purports to describe provisions contained in regulations promulgated by FDA, and respectfully refer the Court to the cited regulatory provisions for a full and complete statement of their contents.

29. Paragraph 29 of the Amended Complaint states the legal opinion and conclusions of Plaintiffs, including a citation to legal authority, as to which no answer is required. To the extent that an answer to these allegations is required, Defendants admit that this paragraph purports to describe provisions contained in regulations promulgated by FDA, and respectfully refer the Court to the cited regulatory provisions for a full and complete statement of their contents.

30. Paragraph 30 of the Amended Complaint states the legal opinion and conclusions of Plaintiffs, including a citation to legal authority, as to which no answer is required. To the extent that an answer to these allegations is required, Defendants admit that this paragraph purports to describe a provision contained in regulations promulgated by FDA, and respectfully refer the Court to the cited regulatory provision for a full and complete statement of its contents.

31. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in the first sentence of paragraph 31 of the Amended Complaint, as that sentence is vague and uses undefined terminology such as “low doses.” With respect to the second sentence of paragraph 31 of the Amended Complaint, Defendants admit

that some antibiotics have been approved for growth promotion indications and otherwise deny the allegations contained in that sentence.

32. Defendants admit that FDA has approved some antibiotics for use in livestock for disease-prevention indications, and deny knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in paragraph 32 of the Amended Complaint, as these allegations are vague and use undefined terminology such as “cramped,” “healthful,” “stress-free,” “tend to occur,” and “less pronounced.”

33. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 33 of the Amended Complaint.

34. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in the first sentence of paragraph 34 of the Amended Complaint. With respect to the second sentence of this paragraph, Defendants admit that the administration of medically important antimicrobials to entire herds or flocks of food-producing animals (e.g., for production purposes) would represent a use that poses a qualitatively higher risk to public health than the administration of such drugs to individual animals or targeted groups of animals (e.g., to prevent, control, or treat specific disease), and otherwise deny the allegations contained in this sentence. The final sentence of paragraph 34 of the Amended Complaint consists of Plaintiffs’ characterization of the Amended Complaint, as to which no answer is required.

35. Defendants admit the allegations contained in paragraph 35 of the Amended Complaint.

36. Defendants admit the allegations contained in paragraph 36 of the Amended Complaint.



37. With respect to the first two sentences of paragraph 37 of the Amended Complaint, Defendants admit that the use of tetracyclines and penicillins in food-producing animals may promote increased bacterial resistance not only to tetracyclines and penicillins but also to other antibiotics. With respect to the allegations contained in the third sentence of paragraph 37 of the Amended Complaint, Defendants admit that aminoglycosides, cephalosporins, and fluoroquinolones are among the available treatments for human infections caused by bacteria that can be transferred from animals to humans and otherwise deny the allegations.

38. Defendants admit the allegations contained in first two sentences of paragraph 38 of the Amended Complaint. Defendants admit the allegations contained in the final sentence of paragraph 38 of the Amended Complaint other than to deny that the Cook County Hospital and the Alliance for the Prudent Use of Antibiotics concluded that the costs as described in that sentence were attributable solely to the use of antibiotics in animals.

39. Defendants admit that the misuse and overuse of antibiotics in livestock may encourage the emergence of antibiotic-resistant bacteria, and otherwise deny the allegations contained in the first sentence of paragraph 39 of the Amended Complaint. Defendants admit the allegations contained in the final three sentences of paragraph 39 of the Amended Complaint.

40. Defendants admit the allegations contained in paragraph 40 of the Amended Complaint.

41. Defendants admit that the use of antibiotics in livestock can contribute to the emergence of antibiotic-resistant bacteria in the animals receiving the antibiotics, which bacteria can sometimes be sources of certain foodborne illness in humans, and otherwise deny the allegations contained in paragraph 41 of the Amended Complaint.

42. Paragraph 42 of the Amended Complaint consists of Plaintiffs' characterization of the Complaint, as to which no answer is required.

43. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the first sentence of paragraph 43 of the Amended Complaint. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the remaining sentences in this paragraph, as those sentences are vague and use undefined terminology such as "frequently," and "various epidemiological studies."

44. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 44 of the Amended Complaint. To the extent that Plaintiffs refer in this paragraph to a study published in 2011 by Waters, *et al.*, and to the extent that an answer to these allegations is required, Defendants respectfully refer the Court to the subject study, and deny these allegations to the extent that the contents of the study differ from the allegations contained in Paragraph 44 of the Amended Complaint.

45. Defendants admit the allegations contained in the first two sentences of paragraph 45 of the Amended Complaint. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in the final sentence of paragraph 45 of the Amended Complaint.

46. Defendants admit the allegations contained in the first sentence of paragraph 46 of the Amended Complaint. With respect to the remaining sentences in this paragraph, Defendants admit that the European Union, Australia and New Zealand prohibit the use of penicillin and tetracyclines for growth promotion indications, and that Japan prohibits the use of penicillin for growth promotion indications, and otherwise deny the allegations contained in those sentences.

47. Defendants admit the allegations contained in paragraph 47 of the Amended Complaint.

48. Defendants admit that FDA approved the use of penicillin as a feed additive in the 1950's and otherwise deny the allegations contained in the first sentence of paragraph 48 of the Amended Complaint. Defendants admit the allegations contained in the second sentence of paragraph 48 of the Amended Complaint.

49. Defendants admit that FDA approved the use of chlortetracycline and oxytetracycline as feed additives in the 1950's and otherwise deny the allegations contained in the first sentence of paragraph 49 of the Amended Complaint. Defendants admit the allegations contained in the second sentence of paragraph 49 of the Amended Complaint.

50. Defendants admit the allegations contained in paragraph 50 of the Amended Complaint.

51. Defendants admit that paragraph 51 of the Amended Complaint purports to summarize some of the findings and conclusions of the task force referred to therein in 1972, and respectfully refer the Court to 37 Fed. Reg. 2444-45 for a more full and complete statement of the findings.

52. Defendants admit that paragraph 52 of the Amended Complaint purports to summarize some of the recommendations of the task force referred to therein in 1972, and respectfully refer the Court to 37 Fed. Reg. 2444-45 for a more full and complete statement of the recommendations.

53. Defendants admit that paragraph 53 of the Amended Complaint constitutes a characterization of statements made by the FDA in 1973, and respectfully refer the Court to 38 Fed. Reg. 9811, 9813 for the full and complete statement.

54. Defendants admit that paragraph 54 of the Amended Complaint constitutes an amalgamation of multiple excerpts of statements made by the FDA in 1977, and respectfully refer the Court to 42 Fed. Reg. 43,722, 43,744-75 for the full and complete statement.

55. Defendants admit that FDA's Bureau of Veterinary Medicine issued the NOOHs in 1977 (respectively, the "penicillin NOOH" and the "tetracycline NOOH"), the full text of which are set forth at 42 Fed. Reg. 43,772 and 42 Fed. Reg. 56,264, and otherwise deny the allegations contained in paragraph 55 of the Amended Complaint.

56. Defendants admit that paragraph 56 of the Amended Complaint constitutes a characterization of the penicillin NOOH, the full text of which is set forth at 42 Fed. Reg. 43,722, *et seq.*

57. Defendants admit that paragraph 57 of the Amended Complaint purports to summarize the penicillin NOOH, the full text of which is set forth at 42 Fed. Reg. 43,722, *et seq.*

58. Defendants admit that paragraph 58 of the Amended Complaint purports to summarize the tetracycline NOOH, the full text of which is set forth 42 Fed. Reg. 56,264, *et seq.*

59. Defendants admit that paragraph 59 of the Amended Complaint purports to summarize the tetracycline NOOH, the full text of which is set forth at 42 Fed. Reg. 56,264, *et seq.*

60. Defendants admit the allegations contained in paragraph 60 of the Amended Complaint.

61. Defendants admit that the report referenced in paragraph 61 of the Amended Complaint concluded that existing data could neither prove nor disprove the postulated hazards to human health from subtherapeutic antimicrobial use in animal feed and that the lack of data linking human illness with subtherapeutic levels of antimicrobials must not be equated with

proof that the proposed hazards do not exist, and otherwise deny the allegations contained in the first sentence of this paragraph. Defendants admit the allegations contained in the second sentence of paragraph 61 of the Amended Complaint.

62. Defendants admit the allegations contained in paragraph 62 of the Amended Complaint.

63. Paragraph 63 of the Amended Complaint purports to characterize a study published in 1984, to which no answer is required. To the extent that an answer to these allegations is required, Defendants respectfully refer the Court to the subject study, and deny these allegations to the extent that the contents of the study differ from the allegations contained in Paragraph 63 of the Amended Complaint.

64. Paragraph 64 of the Amended Complaint purports to characterize a study published in 1988, to which no answer is required. To the extent that an answer to these allegations is required, Defendants respectfully refer the Court to the subject study and deny these allegations to the extent that the contents of the study differ from the allegations contained in Paragraph 64 of the Amended Complaint.

65. Defendants admit that FDA: 1) has concluded that the risks of the subtherapeutic use of tetracycline and penicillin were neither proved nor disproved; 2) did not deny there was some degree of risk; and 3) did not conclude that the subtherapeutic use of penicillin and the tetracycline in animal feed is safe, and otherwise deny the allegations contained in paragraph 65 of the Amended Complaint.

66. Defendants admit that FDA has not revoked the NOOHs and otherwise deny the allegations contained in the first sentence of paragraph 66 of the Amended Complaint. Defendants admit the allegations contained in the second sentence of paragraph 66 of the

Amended Complaint. With respect to the final two sentences of paragraph 66 of the Amended Complaint, Defendants admit that in 1983, the Director of the Center for Veterinary Medicine decided to continue to hold the NOOHs in abeyance pending the outcome of ongoing research, the results of which are the subject of Plaintiffs' allegations in paragraphs 63-64 of the Amended Complaint and otherwise deny these allegations.

67. Defendants admit that, in 2004, FDA sent letters to three manufacturers of animal feed containing penicillin, which expressed certain concerns and assigned the manufacturers' penicillin-containing feed products to a qualitative risk category on the ground that the manufacturers had not submitted information that had been requested by FDA, and otherwise deny the allegations contained in paragraph 67 of the Amended Complaint.

68. Defendants admit that the NOOHs are still pending and that FDA has recently published a series of guidance documents on the subject of antimicrobial resistance, and otherwise deny the allegations contained in paragraph 68 of the Amended Complaint.

69. Defendants admit the allegations contained in paragraph 69 of the Amended Complaint.

70. Defendants admit the allegations contained in paragraph 70 of the Amended Complaint.

71. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the first sentence of paragraph 71 of the Amended Complaint, as those allegations are vague and use undefined terminology such as "stronger than ever." Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in the second sentence of paragraph 71 of the Amended Complaint. With respect to the final sentence of paragraph 71 of the Amended Complaint,

Defendants admit that penicillin and tetracycline are still approved for certain growth promotion indications and otherwise deny these allegations.

72. Defendants deny the allegations contained in the first sentence of paragraph 72 of the Amended Complaint. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in paragraph 72 of the Amended Complaint.

73. Defendants admit the allegations contained in paragraph 73 of the Amended Complaint.

74. Defendants admit the allegations contained in paragraph 74 of the Amended Complaint.

75. Defendants admit the allegations contained in paragraph 75 of the Amended Complaint.

76. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in paragraph 78 of the Amended Complaint, as this paragraph uses vague and undefined terminology such as “frequently,” and “often.”

77. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 77 of the Amended Complaint.

78. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 78 of the Amended Complaint.

79. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 79 of the Amended Complaint.

80. Defendants deny the allegations contained in paragraph 80 of the Amended Complaint.

81. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 81 of the Amended Complaint.

82. Defendants admit the allegations contained in paragraph 82 of the Amended Complaint.

83. Paragraph 83 of the Amended Complaint purports to characterize the subject Citizen Petition, to which no answer is required. To the extent an answer to this paragraph is required, Defendants admit that certain of the Plaintiffs filed a Citizen Petition in 1999 making certain arguments, respectfully refer the Court to that Citizen Petition for a full and complete statement of its contents, deny these allegations to the extent that the contents of that Citizen Petition differs from the allegations contained in Paragraph 83 of the Amended Complaint, and deny that the arguments raised by the petitioners therein were sufficient to justify the requested relief.

84. Paragraph 84 of the Amended Complaint purports to characterize the subject Citizen Petition, to which no answer is required. To the extent that an answer to these allegations is required, Defendants respectfully refer the Court to that Citizen Petition for a full and complete statement of its contents, deny these allegations to the extent that the contents of that Citizen Petition differ from the allegations contained in Paragraph 84 of the Amended Complaint, and deny that the arguments raised by the petitioners therein was sufficient to justify the requested relief.

85. Defendants admit the allegations contained in paragraph 85 of the Amended Complaint.

86. This paragraph purports to characterize the subject Citizen Petition, to which no answer is required. To the extent that an answer to these allegations is required, Defendants



respectfully refer the Court to that Citizen Petition for a full and complete statement of its contents, deny these allegations to the extent that the contents of that Citizen Petition differ from the allegations contained in Paragraph 86 of the Amended Complaint and deny that the arguments raised by the petitioners therein was sufficient to justify the requested relief.

87. Defendants admit the allegations contained in paragraph 87 of the Amended Complaint.

88. Paragraph 88 of the Amended Complaint purports to characterize FDA's interim response to the subject Citizen Petition, as to which no answer is required. To the extent that an answer to these allegations is required, Defendants deny these allegations.

89. Paragraph 89 of the Amended Complaint purports to characterize FDA's interim response to the subject Citizen Petition, as to which no answer is required. To the extent that an answer to these allegations is required, Defendants deny these allegations.

90. Defendants admit the allegations contained in the first sentence of paragraph 90 of the Amended Complaint and deny the allegations contained in the second sentence of this paragraph.

91. Defendants admit the allegations contained in the first two sentences of paragraph 91 of the Amended Complaint. The final sentence of paragraph 91 of the Amended Complaint states the legal opinions and conclusions of the Plaintiff as to which no answer is required. To the extent that this sentence contains factual allegations that may require an answer, Defendants deny those allegations.

92. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 92 of the Amended Complaint.

93. Paragraph 93 of the Amended Complaint states the legal opinions and conclusions of the Plaintiff as to which no answer is required. To the extent that paragraph 93 of the Amended Complaint contains factual allegations that may require an answer, Defendants deny these allegations.

94. Defendants reassert and incorporate by reference herein each of their responses to Paragraphs 1 through 93 of the Amended Complaint as though set forth fully herein.

95. Paragraph 95 of the Amended Complaint states the legal opinions and conclusions of the Plaintiffs, including a citation to legal authority, as to which no answer is required. To the extent that an answer to these allegations is required, Defendants admit that the paragraph purports to describe a provision contained in the FFDCA and refer the Court to the cited statutory provision for a full and complete statement of its contents.

96. Defendants deny the allegations contained in paragraph 96 of the Amended Complaint.

97. Defendants deny the allegations contained in paragraph 97 of the Amended Complaint.

98. Defendants deny the allegations contained in paragraph 98 of the Amended Complaint.

99. Defendants reassert and incorporate by reference herein each of their responses to Paragraphs 1 through 98 of the Amended Complaint as though set forth fully herein.

100. Defendants deny the allegations contained in paragraph 100 of the Amended Complaint.

101. Defendants deny the allegations contained in paragraph 101 of the Amended Complaint.

The remainder of the allegations in the Amended Complaint constitute a prayer for relief, to which no response is required. To the extent an answer is required, Defendants deny that Plaintiffs are entitled to the relief requested therein or to any relief whatsoever.

All allegations not specifically admitted or denied in the foregoing numbered responses are hereby denied.

### AFFIRMATIVE DEFENSES

#### FIRST DEFENSE

The Amended Complaint should be dismissed in whole or in part for failure to state a claim upon which relief can be granted.

#### SECOND DEFENSE

The Amended Complaint should be dismissed in whole or in part on the ground that Plaintiffs' claims are not ripe because Plaintiffs have failed to exhaust their administrative remedies.

Dated: New York, New York  
September 6, 2011

Respectfully submitted,

PREET BHARARA  
United States Attorney  
Southern District of New York

/s/ Amy A. Barcelo  
By: AMY A. BARCELO  
Assistant United States Attorney  
86 Chambers Street  
New York, New York 10007  
Tel.: (212) 637-6559  
Fax: (212) 637-2730  
Email: amy.barcelo@usdoj.gov

OF COUNSEL:

WILLIAM B. SCHULTZ  
Acting General Counsel

ELIZABETH H. DICKINSON  
Acting Chief Counsel

ERIC M. BLUMBERG  
Deputy Chief Counsel, Litigation

THOMAS J. COSGROVE  
Associate Chief Counsel

U.S. Department of Health and Human Services  
Office of the General Counsel, Food and Drug Administration  
White Oak 31 Room 4331  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002  
(Tel): (301) 796-8613