

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

_____ )	
NATURAL RESOURCES DEFENSE )	
COUNCIL, et al., )	
)	
Plaintiffs, )	ANSWER TO FIRST SUPPLEMENTAL
)	COMPLAINT
v. )	11 CIV 3562 (THK)
)	
UNITED STATES FOOD AND DRUG )	ECF CASE
ADMINISTRATION, <i>et al.</i> , )	
)	
Defendants. )	
_____ )	

Defendants, the United States Food and Drug Administration (“FDA”); Margaret Hamburg, in her official capacity as Commissioner of Food and Drugs; 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, the “Defendants”), by their attorney, Preet Bharara, United States Attorney for the Southern District of New York, answer the First Supplemental Complaint for Declaratory and Injunctive Relief (the “Supplemental 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. (“Plaintiffs”) upon information and belief as follows:

1. The first sentence of paragraph 1 of the Supplemental Complaint constitutes Plaintiffs’ characterization of their claims and a legal conclusion of Plaintiffs as to which no answer is required. To the extent a response is required, Defendants deny the allegations contained in that sentence. In response to the second sentence of this paragraph, Defendants

reassert and incorporate by reference herein each of their responses to Plaintiffs' First Amended Complaint for Declaratory and Injunctive Relief ("Amended Complaint").

2. The first sentence of paragraph 2 of the Supplemental Complaint states the legal opinion and conclusions of Plaintiff as to which no answer is required. To the extent that an answer to these allegations is required, Defendants admit that this sentence 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 correct and complete statement of its contents. Defendants admit the remainder of the allegations contained in paragraph 2 of the Supplemental Complaint.

3. With respect to the first sentence of paragraph 3 of the Supplemental Complaint, Defendants admit that FDA issued tentative responses to the Petitions soon after they were filed, and that final responses were issued on November 7, 2011 ("Responses"). The allegations in the second and fourth sentences are admitted. The third sentence contains a characterization of FDA's statements in the Responses, and Defendants respectfully refer the Court to the Responses for a correct and complete statement of their contents.

4. Defendants deny the allegations contained in paragraph 4 of the Supplemental Complaint.

5. Paragraph 5 of the Supplemental Complaint consists of Plaintiffs' characterization of the Supplemental 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.

6. Paragraph 6 of the Supplemental 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, the Defendants deny all such allegations.

7. Paragraph 7 of the Supplemental 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, the Defendants deny all such allegations.

8. Paragraph 8 of the Supplemental 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 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 Supplemental 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 an answer is required, Defendants admit that the Commissioner of Food and Drug is primarily responsible for implementing the FFDCa, and that antibiotics used in animal feed may qualify under the FFDCa as “new animal drugs” when the requisite criteria are satisfied, and otherwise deny the allegations in this paragraph.

10. Paragraph 10 of the Supplemental 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 correct and complete statement of their contents.

11. Defendants admit the allegations contained in paragraph 11 of the Supplemental Complaint.

12. Defendants admit the allegations contained in paragraph 12 of the Supplemental Complaint.

13. Defendants admit the allegations contained in paragraph 13 of the Supplemental Complaint.

14. Defendants admit the allegations contained in paragraph 14 of the Supplemental Complaint.

15. Defendants admit the allegations contained in paragraph 15 of the Supplemental Complaint.

16. Defendants admit that the statement quoted in the first sentence of paragraph 16 of the Supplemental Complaint was made by the Department of Health and Human Services (“HHS”) Office of Inspector General and represented the tentative position of HHS in the form of comments on a draft GAO report, but deny that this statement constituted a final “conclusion” of HHS. Defendants admit on information and belief that the remaining statements by the Centers for Disease Control (“CDC”) were made in a letter from CDC to the Honorable Frank Pallone, Jr. dated July 13, 2010.

17. Defendants admit that the statement quoted in paragraph 17 of the Supplemental Complaint was made by FDA’s Center for Veterinary Medicine, and otherwise deny the allegations contained in this paragraph.

18. Paragraph 18 of the Supplemental Complaint states the legal opinions and conclusions of the Plaintiffs, as to which no answer is required. To the extent that paragraph 18 of the Supplemental Complaint contains factual allegations that may require an answer, Defendants admit that FDA issued tentative responses to the Petitions soon after they were filed, and that the Responses were issued on November 7, 2011.

19. Paragraph 19 of the Supplemental 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 originally filed this action on May 25, 2011, and that Plaintiffs alleged in both their original complaint and the Amended Complaint that FDA's Responses to the Petitions were unreasonably delayed and otherwise deny the allegations in this paragraph.

20. Defendants admit the allegations contained in paragraph 20 of the Supplemental Complaint.

21. Defendants admit the allegations contained in paragraph 21 of the Supplemental Complaint.

22. Defendants admit the allegations contained in paragraph 22 of the Supplemental Complaint.

23. Defendants admit the allegations contained in paragraph 23 of the Supplemental Complaint.

24. Defendants admit the allegations contained in paragraph 24 of the Supplemental Complaint.

25. Defendants admit the statements contained in paragraph 25 of the Supplemental Complaint are attributable to FDA, but deny that they were made "without supporting evidence."

26. Defendants deny the allegations contained in paragraph 26 of the Supplemental Complaint.

27. Defendants admit that the use of antibiotics in livestock may encourage the emergence of antibiotic-resistant bacteria, and otherwise deny the allegations contained in paragraph 27 of the Supplemental Complaint.

28. Defendants admit the allegations contained in paragraph 28 of the Supplemental Complaint.

29. Defendants admit the allegations contained in paragraph 29 of the Supplemental Complaint.

30. Defendants admit the allegations contained in paragraph 30 of the Supplemental Complaint.

31. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in paragraph 31 of the Supplemental Complaint.

32. Defendants deny the allegations contained in paragraph 32 of the Supplemental Complaint.

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

34. Defendants reassert and incorporate by reference herein each of their responses to the Amended Complaint and to Paragraphs 1 through 33 of the Supplemental Complaint as though set forth fully herein.

35. Paragraph 35 of the Supplemental 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, the Defendants deny all such allegations.

36. Defendants deny the allegations contained in paragraph 36 of the Supplemental Complaint.

37. Defendants deny the allegations contained in paragraph 37 of the Supplemental Complaint.

38. Defendants deny the allegations contained in paragraph 38 of the Supplemental Complaint.

The remainder of the allegations in the Supplemental 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 Supplemental Complaint should be dismissed in whole or in part for failure to state a claim upon which relief can be granted.

SECOND DEFENSE

The Supplemental Complaint should be dismissed in whole or in part on the ground that no subject matter jurisdiction exists over their claims.

Dated: New York, New York  
February 21, 2011

Respectfully submitted,

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Southern District of New York

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