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

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, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; MARGARET HAMBURG, in her official capacity as Commissioner, United States Food and Drug Administration; 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 Defendants.	)	11 CIV 3562 (THK) ECF Case

THE GOVERNMENT'S RESPONSE TO PLAINTIFFS' STATEMENT OF UNDISPUTED MATERIAL FACTS PURSUANT TO LOCAL CIVIL RULE 56.1

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 ("HHS"); and Kathleen Sebelius, in her official capacity as Secretary, United States Department of Health and Human Services (collectively, the "Government"), by their attorney, Preet Bharara, United States Attorney for the Southern District of New York, respond to the Statement of Undisputed Material Facts In Support of Motion for Summary Judgment on Their Third Claim for Relief ("Plaintiffs' Statement") submitted by Plaintiffs Natural Resources Defense Council, Center for Science in the Public Interest, Food Animal Concerns Trust, Public Citizen, and Union of Concerned Scientists (collectively, "Plaintiffs"). In responding to Plaintiffs' Statement, the Government not concede the materiality of any of the statements and specifically reserves the right to object that Plaintiffs' assertedly undisputed facts are immaterial and do not support Plaintiffs' motion for summary judgment. The Government responds as follows:

1. Plaintiffs incorporate by reference paragraphs 1-4, 6-19, 23-24, 26-29, 32-43, and 68 of their Statement of Undisputed Material Facts in Support of Motion for Summary Judgment, Oct. 6, 2011 (Dkt. 21).

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government incorporates by reference paragraphs 1-4, 6-17, 19, 23-24, 26-29, 32-43, and 68 of its Responses to Plaintiffs' Statement of Undisputed Material Facts Pursuant to Local Civil Rule 56.1, dated January 9, 2012. (Dkt. No. 45). The Government does not controvert the statement made in paragraph 18 of Plaintiffs Statement of Undisputed Material Facts in Support of Motion for Summary Judgment dated Oct. 6, 2011.

2. On March 9, 1999, CSPI, FACT, Public Citizen, and UCS submitted a petition to FDA requesting that the agency "rescind approvals for subtherapeutic uses in livestock of any antibiotic used in (or related to those used in) human medicine." Citizen Petition 1-2 (Mar. 9, 1999), Ex. I to Decl. of Jennifer A. Sorenson, Oct. 5, 2011 (Sorenson Decl.) (Dkt. 33-9).

NOT CONTROVERTED.

3. On April 7, 2005, FACT and UCS submitted a second petition to FDA. The petition requested that the FDA Commissioner "withdraw approvals for herdwide/flockwide uses of [specific] antibiotics in chicken, swine, and beef cattle for purposes of growth promotion (including weight gain and feed efficiency) and disease prevention and control (except for non-routine use where a bacterial infection has been diagnosed within a herd or flock)." Citizen Petition 1 (Apr. 7, 2005), Sorenson Decl. Ex. K (Dkt. 33-11). The petition covered penicillins, tetracyclines, aminoglycosides, streptogramins, macrolides, lincomycin, and sulfonamides. *Id.*

NOT CONTROVERTED.

4. FDA delayed ruling on the petitions for twelve and six years respectively.

CONTROVERTED. FDA provided a tentative, but substantive, response to the citizen petition submitted by plaintiffs Center for Science in the Public Interest, Food Animal Concerns Trust ("FACT"), Public Citizen, Inc., and Union of Concerned Scientists, Inc. ("UCS") to FDA on March 9, 1999 (the "1999 Petition") on February 28, 2001. *See* Declaration of Amy A. Barcelo dated March 21, 2012 ("Second Barcelo Decl."), Ex. F. FDA provided a tentative, but substantive, response to the citizen petition submitted by FACT and UCS on April 7, 2005 (the "2005 Petition"), on October 4, 2005, respectively. *See* Second Barcelo Decl. Ex. G. On November 7, 2011, FDA issued final responses to the 1999 Petition and the 2005 Petition (the "Petition Responses"). *See* Declaration of Amy A. Barcelo dated January 9, 2012 ("Jan. Barcelo Decl."), Exs. I & J.

5. In 2010, FDA issued Draft Guidance No. 209, which concludes that "using medically important antimicrobial drugs for production purposes [i.e., increasing rate of weight gain or improving feed efficiency] is not in the interest of protecting and promoting the public health." FDA, Draft Guidance No. 209, at 13 (June 28, 2010), Sorenson Decl. Ex. O (Dkt. 33-15).

NOT CONTROVERTED.

6. Draft Guidance No. 209 recommends that medically important antibiotics be used in food-producing animals (1) only when necessary to ensure the animals' health, and not to promote growth or improve feed efficiency, and (2) only with veterinary oversight. *Id.* at 16-17.

NOT CONTROVERTED.

7. On November 7, 2011, FDA denied both citizen petitions.

NOT CONTROVERTED.

8. In its final responses to both petitions, FDA stated that "we share your concern about the use of medically important antimicrobial drugs in food-producing animals for growth promotion and feed efficiency indications (i.e., production uses)." Final Response to Citizen Petition, New Dkt. No. FDA-1999-P-1286 (Denial of 1999 Petition), at 1 (Nov. 7, 2011), Ex. A to Decl. of Mitchell S. Bernard, Feb. 21, 2012 (Bernard Decl.); Final Response to Citizen Petition, New Dkt. No. FDA-2005-P-0007 (Denial of 2005 Petition), at 1 (Nov. 7, 2011), Bernard Decl. Ex. B.

NOT CONTROVERTED.

9. The petition denials do not address the science underlying the petitions.

CONTROVERTED. The Government controverts paragraph 8 of Plaintiffs' Statement of

Undisputed Material Facts in Support of Motion for Summary Judgment on Their Third Claim for Relief on the grounds that it is vague in that it does not explain what it means by "address the science underlying the petitions." In the Petition Responses, the United States Food and Drug Administration stated that "we share your concern about the use of medically important antimicrobial drugs in food-producing animals for growth promotion and feed efficiency indications (i.e., production uses)." Jan. Barcelo Decl. Ex. I at 1, Ex. J at 1.

10. In denying the petitions, FDA stated that "for various reasons the Agency has decided not to institute formal withdrawal proceedings at this time and instead is currently pursuing other alternatives to address the issue of antimicrobial resistance related to the production use of antimicrobials in animal agriculture." Denial of 1999 Petition 3; Denial of 2005 Petition 2.

NOT CONTROVERTED.

11. The alternative strategy identified by FDA in the petition denials is the "strategy set out in draft guidance #209." Denial of 1999 Petition 4; Denial of 2005 Petition 4.

NOT CONTROVERTED.

12. Draft Guidance No. 209 has not yet been finalized.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that FDA Draft Guidance for Industry #209, *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals* (2010) ("Draft Guidance 209"), has not yet been finalized, but does controvert this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

NOT CONTROVERTED .

13. When final, Draft Guidance No. 209 will "not establish legally enforceable responsibilities." Draft Guidance No. 209, at 2.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that, when finalized, Draft Guidance 209 will not establish legally enforceable responsibilities, but does controvert this statement as not a statement of fact material to the claims of the

Plaintiffs or the defenses of the Government.

Dated: New York, New York
March 21, 2012

Respectfully submitted,

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