

**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,	)	11 CIV 3562 (THK)
	)	ECF Case
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.	)	
	)	

**PLAINTIFFS’ STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF  
MOTION FOR SUMMARY JUDGMENT ON THEIR THIRD CLAIM FOR RELIEF**

Plaintiffs Natural Resources Defense Council, Center for Science in the Public Interest (CSPI), Food Animal Concerns Trust (FACT), Public Citizen, and Union of Concerned Scientists (UCS) respectfully submit this Statement of Undisputed Material Facts in support of their Motion for Summary Judgment on their Third Claim for Relief.

Pursuant to Federal Rule of Civil Procedure 56 and this Court’s Local Civil Rule 56.1, there is no genuine issue as to the following facts:

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).

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).

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.*

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

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).

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.

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

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.

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

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.

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.

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 Draft Guidance No. 209 has not yet been finalized.

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 When final, Draft Guidance No. 209 will “not establish legally enforceable responsibilities.” Draft Guidance No. 209, at 2.

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Dated: February 21, 2012

Respectfully submitted,

s/ Mitchell S. Bernard  
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