

**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' NOTICE OF MOTION FOR SUMMARY JUDGMENT
ON THEIR THIRD CLAIM FOR RELIEF**

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, plaintiffs Natural Resources Defense Council, Center for Science in the Public Interest, Food Animal Concerns Trust, Public Citizen, and Union of Concerned Scientists hereby move for summary judgment on their Third Claim for Relief, on the basis that there is no genuine issue of material fact, and plaintiffs are entitled to judgment as a matter of law. Defendants' denials of plaintiffs' citizen petitions are contrary to the Federal Food, Drug, and Cosmetic Act (Food and Drug Act), 21 U.S.C. § 360b(e)(1), and lack a reasoned basis, in violation of the Administrative Procedure Act (APA),

5 U.S.C. § 706(2). The denials must be set aside as “arbitrary, capricious, . . . or otherwise not in accordance with law.” *Id.* § 706(2)(A).

The citizen petitions, submitted by plaintiffs in 1999 and 2005, requested that the U.S. Food and Drug Administration (FDA) withdraw approvals for nontherapeutic uses of medically important antibiotics in livestock, on the ground that these drug uses present human health risks. FDA denied the petitions in November 2011. Refusing to engage with the scientific evidence on which the petitioners relied, the agency denied the petitions in favor of an unenforceable plea for industry cooperation. FDA’s approach finds no basis in the Food and Drug Act and is thus “not in accordance with law” within the meaning of the APA. *Id.* Moreover, FDA failed to articulate a rational connection between its own conclusion that the challenged drug uses jeopardize human health and its decision not to take binding action. Nor has the agency presented a shred of evidence that its alternative, extrastatutory method will work. The lack of such evidence deprives FDA’s action of a reasoned basis, in further violation of the APA. For these reasons, plaintiffs seek an order vacating the denials and remanding the matter to FDA with instructions to address the petitions promptly on their merits.

In support of this motion, plaintiffs submit the accompanying (1) memorandum of law in support of plaintiffs’ motion for summary judgment on their Third Claim for Relief; (2) statement of material facts as to which there is no genuine dispute; and (3) declaration of Mitchell S. Bernard and accompanying exhibits.

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Dated: February 21, 2012

Respectfully submitted,

s/ Mitchell S. Bernard

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