

**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

PLAINTIFFS’ MOTION FOR SUMMARY JUDGMENT

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 the basis that there is no genuine issue of material fact, and plaintiffs are entitled to judgment as a matter of law. Defendants have violated (1) the Federal Food, Drug, and Cosmetic Act (Food and Drug Act), 21 U.S.C. § 360b(e)(1)(B), by failing to withdraw approvals for subtherapeutic uses of

penicillin and tetracyclines in animal feed and (2) the Administrative Procedure Act (APA), 5 U.S.C. § 555(b), by delaying unreasonably in ruling on plaintiffs' citizen petitions.

The Food and Drug Act requires the U.S. Food and Drug Administration (FDA) to withdraw approval of an animal drug if the agency finds that the drug is not shown to be safe for human health. More than three decades ago, FDA found that certain subtherapeutic uses of penicillin and tetracyclines in animal feed were not shown to be safe, because they promoted the development of antibiotic-resistant bacteria that could be transferred to humans. FDA has never retracted its findings, nor could it, consistent with current science and the agency's own pronouncements. Yet, despite the statutory requirement that it do so, FDA has not withdrawn its approvals for penicillin and tetracyclines in animal feed. By failing to withdraw these approvals, FDA has unlawfully withheld agency action. *See* APA, 5 U.S.C. § 706(1).

Several of the plaintiffs in this action submitted citizen petitions to FDA in 1999 and 2005, requesting that the agency withdraw approvals for nontherapeutic uses of antibiotics in livestock if those antibiotics are also important to human medicine. Twelve and six years later, the agency has not ruled on either petition. FDA's delay in ruling on the plaintiffs' petitions is unreasonable. *See id.*

In support of this motion, plaintiffs submit the accompanying (1) memorandum of law in support of plaintiffs' motion for summary judgment; (2) statement of material facts as to which there is no genuine dispute; (3) Declaration of Jasanna Britton; (4) Declaration of Amanda J. Fleming; (5) Declaration of Dennis Haller; (6) Declaration of Michael F. Jacobson; (7) Declaration of Max Kahn, and attached exhibit; (8) Declaration of Anne Kapuscinski; (9) Declaration of Linda Lopez; (10) Declaration of Melissa Melum; (11) Declaration of Rachel Mlinarchik; (12) Declaration of Jennifer Norris; (13) Declaration of Ilana Slaff-Galatan; (14)

Declaration of Jennifer A. Sorenson, and attached exhibits; (15) Declaration of Robert Weissman; and (16) Declaration of Richard Wood.

Dated: October 6, 2011

Respectfully submitted,

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s/ Jennifer A. Sorenson
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