

**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’ RESPONSE TO THE GOVERNMENT’S STATEMENT OF
UNDISPUTED MATERIAL FACTS PURSUANT TO LOCAL CIVIL RULE 56.1**

Plaintiffs Natural Resources Defense Council, Center for Science in the Public Interest, Food Animal Concerns Trust, Public Citizen, and Union of Concerned Scientists respond to the Statement of Undisputed Material Facts Pursuant to Local Civil Rule 56.1 submitted on January 9, 2012, by Defendants United States Food and Drug Administration (FDA); Margaret Hamburg, in her official capacity as Commissioner, FDA; Center for Veterinary Medicine (CVM); Bernadette Dunham, in her official capacity as Director, CVM; United States Department of

Health and Human Services (HHS); and Kathleen Sebelius, in her official capacity as Secretary, HHS. Plaintiffs respond as follows:

1. In 1977, FDA's Bureau of Veterinary Medicine issued two notices of opportunity for hearing that generally proposed to withdraw approval of penicillin and tetracycline in animal feed because of safety concerns related to those uses (collectively, the "1977 NOOHs"). *See* Penicillin-Containing Premixes; Opportunity for Hearing, 42 Fed. Reg. 43772 (Aug. 30, 1977) (the "Penicillin NOOH"), attached as Exhibit D to Barcelo Decl.; Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes; Opportunity for Hearing, 42 Fed. Reg. 56264 (Oct. 21, 1977) (the "Tetracycline NOOH"), attached as Exhibit E to the Barcelo Decl.

NOT CONTROVERTED.

2. The Tetracycline NOOH included a series of important exceptions, through which the use of tetracycline feeds would remain approved for certain "subtherapeutic conditions of use." Tetracycline NOOH, 42 Fed. Reg. at 56287.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. Plaintiffs do not controvert that FDA carved out seven limited exceptions from its proposal to withdraw "all approvals for tetracycline-containing premix products intended for subtherapeutic uses in animal feed . . . on the grounds that they have not been shown to be safe." Tetracycline NOOH, 42 Fed. Reg. at 56,287-88. Plaintiffs do controvert, as unsupported, Defendants' contention that these exceptions are "important."

3. In response to the 1977 NOOHs, approximately 20 drug firms, agricultural organizations and individuals requested hearings on BVM's proposals as set forth in the 1977 NOOHs. *See* Penicillin and Tetracycline in Animal Feeds Hearing, 43 Fed. Reg. 53827, 53828 (Nov. 17, 1978), attached as Exhibit G to the Barcelo Decl.

NOT CONTROVERTED.

4. On November 9, 1978, the Commissioner granted these requests, announcing that "there w[ould] be a formal evidentiary public hearing on these proposals," and that a date for the hearing would be set "as soon as practicable." *See* Penicillin and Tetracycline in Animal Feeds Hearing, 43 Fed. Reg. at 53828.

NOT CONTROVERTED.

5. In the late 1970s and early 1980s, Congress requested that FDA conduct further studies and hold in abeyance the implementation of the 1977 NOOHs pending the outcome of these studies. *See* H.R. Rep. No. 95-1290, at 99-100 (1978) (report by the House Committee on Appropriations “recommend[ing]” that FDA conduct research regarding “whether or not the continued subtherapeutic use of [the NOOH Products] would result in any significant human health risk” before revoking such approval); H.R. Rep. No. 96-1095, at 105-06 (1980) (report by the House Committee on Appropriations requesting FDA to “hold in abeyance any implementation” of the proposed revocation pending further research); S. Rep. No. 97-248, at 79 (1981) (report by the Senate Committee on Appropriations making the same request); *see also* FDA Draft Guidance for Industry #209, *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals* (2010) at 6, attached as Exhibit B to the Barcelo Decl.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. Plaintiffs do not controvert that H.R. Rep. No. 95-1290 (1978), a report by the House Committee on Appropriations; H.R. Rep. No. 96-1095 (1980), a report by the House Committee on Appropriations; and S. Rep. No. 97-248 (1981), a report by the Senate Committee on Appropriations, contain the statements attributed to them in paragraph 5 of Defendants’ 56.1 Statement. Plaintiffs do controvert that these nonbinding reports by congressional committees amount to requests by “Congress.” *See Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 191 (1978) (“Expressions of committees dealing with requests for appropriations cannot be equated with statutes enacted by Congress”); *id.* at 189-92; *Nw. Envtl. Def. Ctr. v. Bonneville Power Admin.*, 477 F.3d 668, 682 (9th Cir. 2007) (explaining that language in an appropriations committee report that is “unconnected to the text of an enacted statute has no binding legal import”). Plaintiffs further controvert this statement as not a statement of fact material to Plaintiffs’ claims or Defendants’ defenses.

6. No hearing has been held in connection with the 1977 NOOHs. *See* Withdrawal of Notices of Opportunity for a Hearing; Penicillin and Tetracycline used in Animal Feed, 76 Fed. Reg. 79697, 79698 (Dec. 22, 2011), attached as Exhibit L to Barcelo Decl.

NOT CONTROVERTED.

7. On December 16, 2011, FDA withdrew the 1977 NOOHs. See 76 Fed. Reg. 79697.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. Plaintiffs do not controvert that FDA withdrew the 1977 NOOHs in a notice published in the Federal Register on December 22, 2011. Plaintiffs controvert this statement as not a statement of fact material to Plaintiffs' claims or Defendants' defenses.

Dated: January 31, 2012

Respectfully submitted,

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