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UNITED STATES DISTRICT COURT
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
www.fCommissioner, 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 STATEMENT OF UNDISPUTED MATERIAL FACTS
PURSUANT TO LOCAL CIVIL RULE 56.1

Pursuant to Civil Rule 56.1 of the Local Civil Rules of the United States District Court for the Southern District of New York, 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, state that there is no genuine issue to be tried with respect to the following material facts:

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.

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.

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.

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.

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.

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.

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

Dated: New York, New York
January 9, 2012

Respectfully submitted,

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