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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
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

Amy A. Barcelo, pursuant to the provisions of 28 U.S.C. § 1746, declares, under penalty
of perjury, as follows:

1. I am Assistant United States Attorney in the office of Preet Bharara, United States Attorney for the Southern District of New York, attorney for defendants in this case. I am the attorney assigned to the defense of this matter.

2. I submit this declaration in support of the defendants' motion for summary judgment.

3. Attached as Exhibit A hereto is a true and correct copy of § 1410.10 of Volume II of the United States Food and Drug Administration ("FDA") Staff Manual Guides (the "Staff Manual Guides"), *Delegations of Authority to the Commissioner Food and Drug*; and § 1410.503 of Volume II of the Staff Manual Guides, *Issuance of Notices, Proposals, and Orders Relating to New Animal Drugs and Medicated Feed Mill License Applications*. A copy of the entire Staff Manual Guides is available at:

<http://www.fda.gov/aboutfda/reportsmanualsforms/staffmanualguides/default.htm>.

4. Attached as Exhibit B hereto is a true and correct copy of FDA Draft Guidance for Industry #209, *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals* (2010), which is available at:

<http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm216936.pdf>.

5. Attached as Exhibit C hereto is a true and correct copy of Questions and Answers on FDA's Draft Guidance on the Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals, which is available at:

<http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm216939.htm>.

6. Attached as Exhibit D hereto is a true and correct copy of Penicillin-Containing Premixes; Opportunity for Hearing, 42 Fed. Reg. 43772 (Aug. 30, 1977).
7. Attached as Exhibit E hereto is a true and correct copy of Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes; Opportunity for Hearing, 42 Fed. Reg. 56264 (Oct. 21, 1977).
8. Attached as Exhibit F hereto is a true and correct copy of Antibiotic and Sulfonamide Drugs in Animal Feeds; Proposed Statement of Policy, 37 Fed. Reg. 2444 (Feb. 1, 1972).
9. Attached as Exhibit G hereto is a true and correct copy of Penicillin and Tetracycline in Animal Feeds Hearing, 43 Fed. Reg. 53827 (November 17, 1978).
10. Attached as Exhibit H hereto is a true and correct copy of FDA Guidance for Industry #152, *Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern* (2003), which is available at: <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052519.pdf>.
11. Attached as Exhibit I hereto is a true and correct copy of the November 7, 2011 FDA Final Response to Citizen Petition New Docket No. FDA-1999-P-1286 addressed to Sarah Klein.
12. Attached as Exhibit J hereto is a true and correct copy of the November 7, 2011 FDA Final Response to Citizen Petition New Docket No. FDA-2005-P-0007, addressed to Andrew Maguire.
13. Attached as Exhibit K hereto is a true and correct copy of Advance Notice of Proposed Rulemaking, 75 Fed. Reg. 15387 (March 29, 2010).

14. Attached as Exhibit L hereto is a true and correct copy of Withdrawal of Notices of Opportunity for a Hearing; Penicillin and Tetracycline used in Animal Feed, 76 Fed. Reg. 79697 (Dec. 22, 2011).

15. Attached as Exhibit M hereto is a true and correct copy of 21 C.F.R. § 5.84 (1977).

16. Attached as Exhibit N hereto is a true and correct copy of Final Decision of the Commissioner, Withdrawal of Approval of the New Animal Drug Application for Enrofloxacin in Poultry, Docket No. 2000N-1571 (July 27, 2005).

17. Attached as Exhibit O hereto is a true and correct copy of Nitrofurans; Withdrawal of Approved New Animal Drug Applications (Nitrofurans), 56 Fed. Reg. 41902 (Aug. 23, 1991).

18. Attached as Exhibit P hereto is a true and correct copy of Diethylstilbestrol; Withdrawal of New Animal Drug Applications (DES), 44 Fed. Reg. 54852 (Sept. 21, 1979).

I declare under penalty of perjury that the foregoing is true and correct.

Dated: New York, New York
January 9, 2012

/s/ Amy A. Barcelo
AMY A. BARCELO
Assistant United States Attorney