

**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

**DECLARATION OF
JENNIFER A. SORENSON**

I, Jennifer A. Sorenson, declare as follows:

1. I serve as counsel for plaintiffs in this proceeding. I am a member in good standing of the bar of the State of California, and I am admitted to practice *pro hac vice* in this action. I have personal knowledge of the facts stated herein.

2. Attached as Exhibit A is a true and correct copy of Penicillin-Containing Premixes, 42 Fed. Reg. 43,772 (Aug. 30, 1977).

3. Attached as Exhibit B is a true and correct copy of Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes, 42 Fed. Reg. 56,264 (Oct. 21, 1977).

4. Attached as Exhibit C is a true and correct copy of Antibiotic and Sulfonamide Drugs in Animal Feeds, 37 Fed. Reg. 2444 (Feb. 1, 1972).

5. Attached as Exhibit D is a true and correct copy of Antibiotic and Sulfonamide Drugs in the Feed of Animals, 38 Fed. Reg. 9811 (Apr. 20, 1973).

6. Attached as Exhibit E is a true and correct copy of New Animal Drugs; Removal of Obsolete and Redundant Regulations, 68 Fed. Reg. 47,272 (Aug. 8, 2003).

7. Attached as Exhibit F is a true and correct copy of an excerpt from National Academy of Sciences, *The Effects on Human Health of Subtherapeutic Use of Antimicrobials in Animal Feeds* (1980). I downloaded this document in March 2011 from www.regulations.gov (search U.S. Food and Drug Administration (FDA) docket no. 2010-D-0094).

8. Attached as Exhibit G is a true and correct copy of an excerpt from Seattle-King County Department of Public Health, Communicable Disease Control Section, *Surveillance of the Flow of Salmonella and Campylobacter in a Community* (1984). I downloaded this document in April 2011 from www.regulations.gov (search FDA docket no. 2010-D-0094).

9. Attached as Exhibit H is a true and correct copy of an excerpt from Institute of Medicine, *Human Health Risks with the Subtherapeutic Use of Penicillin and Tetracyclines in Animal Feed* (1988). I downloaded this document in March 2011 from www.regulations.gov (search FDA docket no. 2010-D-0094).

10. Attached as Exhibit I is a true and correct copy of a Citizen Petition submitted by plaintiffs Center for Science in the Public Interest (CSPI), Food Animal Concerns Trust (FACT), Public Citizen, and Union of Concerned Scientists (UCS) to FDA (Mar. 9, 1999).

11. Attached as Exhibit J is a true and correct copy of a Letter from Stephen F. Sundlof, Director, Center for Veterinary Medicine (CVM), to Michael F. Jacobson, Executive Director, CSPI (Feb. 28, 2001).
12. Attached as Exhibit K is a true and correct copy of a Citizen Petition submitted by plaintiffs FACT and UCS to FDA (Apr. 7, 2005).
13. Attached as Exhibit L is a true and correct copy of a Letter from Stephen F. Sundlof, Director, CVM, to Karen Florini, Senior Attorney, Environmental Defense (Oct. 4, 2005).
14. Attached as Exhibit M is a true and correct copy of FDA, Guidance for Industry No. 152, *Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern* (2003).
15. Attached as Exhibit N are true and correct copies of Letters from Stephen F. Sundlof, Director, CVM, to Carol A. Wrenn, President, Animal Health Division, Alpharma Inc.; Gregory P. Bergt, Director, Regulatory Affairs, Pennfield Oil Company; and Norma A. Buckart, Manager, Regulatory Affairs, Phibro Animal Health (May 26, 2004).
16. Attached as Exhibit O is a true and correct copy of FDA, Draft Guidance No. 209, *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals* (2010).
17. Attached as Exhibit P is a true and correct copy of FDA, *2009 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals* (2010).
18. Attached as Exhibit Q is a true and correct copy of a Letter, with enclosure, from Karen Meister, Supervisory Congressional Affairs Specialist, FDA, to the Honorable Louise M. Slaughter, House of Representatives (Apr. 19, 2011).

19. Attached as Exhibit R is a true and correct copy of Statement of Joshua M. Sharfstein, M.D., Principal Deputy Commissioner, FDA, before the Subcommittee on Health, Committee on Energy and Commerce, United States Congress (July 14, 2010).

20. Attached as Exhibit S is a true and correct copy of FDA, *Consumer Health Information: Combating Antibiotic Resistance* (updated Dec. 2010). I downloaded this document in September 2011, using the following URL:

<http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM143470.pdf>.

21. Attached as Exhibit T is a true and correct copy of FDA, *Battle of the Bugs: Fighting Antibiotic Resistance*. I downloaded this document in September 2011, using the following URL: <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143568.htm>.

22. Attached as Exhibit U is a true and correct copy of FDA, *Public Health Focus: Antimicrobial Resistance*. I downloaded this document in September 2011, using the following URL: <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm235649.htm>.

23. Attached as Exhibit V is a true and correct copy of an excerpt from National Antimicrobial Resistance Monitoring System, *2009 Retail Meat Report*.

24. Attached as Exhibit W is a true and correct copy of a Letter, with enclosure, from Thomas R. Frieden, Director, Centers for Disease Control and Prevention (CDC), to the Honorable Frank Pallone, Jr., Chairman, Subcommittee on Health, House Committee on Energy and Commerce (July 13, 2010).

25. Attached as Exhibit X is a true and correct copy of CDC, *Antibiotic Resistance Questions and Answers* (updated June 30, 2009). I downloaded this document in September 2011, using the following URL: <http://www.cdc.gov/getsmart/antibiotic-use/antibiotic-resistance-faqs.html>.

26. Attached as Exhibit Y is a true and correct copy of an excerpt from U.S. General Accounting Office (GAO), *Antibiotic Resistance: Federal Agencies Need to Better Focus Efforts to Address Risk to Humans from Antibiotic Use in Animals* (2004).

27. Attached as Exhibit Z is a true and correct copy of an excerpt from Institute of Medicine, *Microbial Threats to Human Health: Emergence, Detection, and Response* (Mark S. Smolinski, Margaret A. Hamburg & Joshua Lederberg eds., 2003).

28. Attached as Exhibit AA is a true and correct copy of World Health Organization (WHO), World Health Day 2011, Policy Brief No. 4D, *Reduce Use of Antimicrobials in Food-Producing Animals* (2011).

29. Attached as Exhibit BB is a true and correct copy of WHO, World Health Day 2011, *Frequently Asked Questions* (2011).

30. Attached as Exhibit CC is a true and correct copy of an excerpt from GAO, *Antibiotic Resistance: Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals* (2011).

31. Attached as Exhibit DD is a true and correct copy of Penicillin and Tetracycline in Animal Feeds, 48 Fed. Reg. 4554 (Feb. 1, 1983).

I declare under penalty of perjury that the foregoing is true and correct, to the best of my knowledge, information, and belief.

Executed on October 5, 2011, at San Francisco, California.


Jennifer A. Sorenson