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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

THIRD DECLARATION OF AMY A. BARCELO

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 Attached as Exhibit A hereto is a copy of United States Food and Drug Administration ("FDA") Draft Guidance for Industry #209, *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals*.
- 4. Attached as Exhibit B hereto is a copy of FDA Draft Guidance for Industry #213, New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209.
- 5. Attached as Exhibit C hereto is a copy of the Draft Text for Proposed Regulation entitled Veterinary Feed Directive; Draft Text for Proposed Regulation, for inclusion in 21 C.F.R. Part 558, issued by FDA on April 11, 2011.
- 6. Attached as Exhibit D hereto is a true and correct copy of a Press Release dated March 1, 2011, by Pfizer Inc., entitled "Pfizer Completes Acquisition of King Pharmaceuticals, Inc.," which is available at:

http://www.businesswire.com/news/home/20110301006102/en/Pfizer-Completes-Acquisition-King-Pharmaceuticals.

7. Attached as Exhibit E hereto is a true and correct copy of an excerpt from the website of the American Farm Bureau Federation, which is available at: http://www.fb.org/index.php?action=about.home.

8. Attached as Exhibit F hereto is a true and correct copy of a statement issued by

the American Health Institute on April 11, 2012, which is available at:

http://www.ahi.org/archives/2012/04/ahi-statement-on-fda-guidance-documents-and-draft-on-fda-guidanc

codified-language-on-antibiotics/.

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

Dated: New York, New York April 16, 2012

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