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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

**SECOND 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 Center for Veterinary Medicine, Program Policy and Procedure Manual, Voluntary Compliance, which is available at: <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/PoliciesProceduresManual/ucm046435.pdf>. 4.

4. Attached as Exhibit B hereto is a Fed FDA Regulatory Procedures Manual, § 4-1-1, which is available at: <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176870.htm>

5. Attached as Exhibit C hereto is FDA Investigations Operations Manual, § 2.6.1, which is available at: <http://www.fda.gov/ICECI/Inspections/IOM/ucm122514.htm>

6. Attached as Exhibit D hereto is the citizen petition submitted by plaintiffs Center for Science in the Public Interest, Food Animal Concerns Trust ("FACT"), Public Citizen, Inc., and Union of Concerned Scientists, Inc. ("UCS") submitted citizen petition to FDA on March 9, 1999 (the "1999 Petition"). This document is included in the Administrative Record of the citizen petitions: (1) filed with FDA on March 9, 1999, by plaintiffs Center for Science in the Public Interest, FACT, Public Citizen, Inc., and UCS submitted citizen petition to FDA, and (2) filed with FDA on April 7, 2005, by plaintiffs FACT and UCS, filed by the defendants in this action on March 21, 2012, under the Certification of Karen Kennard, Division of Dockets Management, executed on March 20, 2012 (the "Administrative Record").

7. Attached as Exhibit E hereto is the citizen petition submitted by plaintiffs FACT and UCS to FDA on April 7, 2005 (the “2005 Petition”). This document is included in the Administrative Record.

8. Attached as Exhibit F hereto is FDA’s tentative response to the 1999 Petition, dated February 28, 2001. This document is included in the Administrative Record.

9. Attached as Exhibit G hereto is FDA’s tentative response to the 2005 Petition, dated October 4, 2005. This document is included in the Administrative Record.

10. Attached as Exhibit H hereto is the slip opinion in *Chaney v. Schweiker*, No. 81-2265 (D.D.C. Aug. 30, 1982).

11. Attached as Exhibit I hereto is an excerpt from the 1947 Attorney General’s Manual on the Administrative Procedure Act consisting of pages 8-17 of that Manual.

12. The documents attached as Exhibits B, H, I, and J to my declaration dated January 9, 2012 in this action are included in the Administrative Record.

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

Dated: New York, New York  
March 21, 2012

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