

PREET BHARARA  
United States Attorney for the  
Southern District of New York  
By: AMY A. BARCELO  
Assistant United States Attorney  
86 Chambers Street, 3rd Floor  
New York, New York 10007  
Telephone: (212) 637-6559  
Fax: (212) 637-2730  
amy.barcelo@usdoj.gov

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 IN RESPONSE TO CLAIM SET FORTH IN  
PLAINTFFS' FIRST SUPPLEMETNAL COMPLAINT**

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; 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. The administrative record of the citizen petitions: (1) filed with FDA on March 9, 1999, by plaintiffs Center for Science in the Public Interest, Food Animal Concerns Trust (“FACT”), Public Citizen, Inc., and Union of Concerned Scientists, Inc. (“UCS”) and (2) filed with FDA on April 7, 2005, by plaintiffs FACT and UCS submitted a citizen petition to FDA (collectively, the “Citizen Petitions”), filed in this action by the Government on March 21, 2012; under the Certification of Karen Kennard, Division of Dockets Management, executed on March 20, 2012, constitutes the administrative record upon which FDA denied the Citizen Petitions.

Dated: New York, New York  
March 21, 2012

Respectfully submitted,

PREET BHARARA  
United States Attorney  
Southern District of New York

/s/ Amy A. Barcelo

By: AMY A. BARCELO  
Assistant United States Attorney  
86 Chambers Street  
New York, New York 10007  
Tel.: (212) 637-6559  
Fax: (212) 637-2730  
Email: amy.barcelo@usdoj.gov

OF COUNSEL:

DAVID J. HOROWITZ  
Deputy General Counsel

ELIZABETH H. DICKINSON  
Acting Chief Counsel, Food and Drug  
Division

ERIC M. BLUMBERG  
Deputy Chief Counsel, Litigation

THOMAS J. COSGROVE  
Associate Chief Counsel

U.S. Department of Health and Human Services  
Office of the General Counsel  
White Oak 31 Room 4331  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002  
(Tel): (301) 796-8613