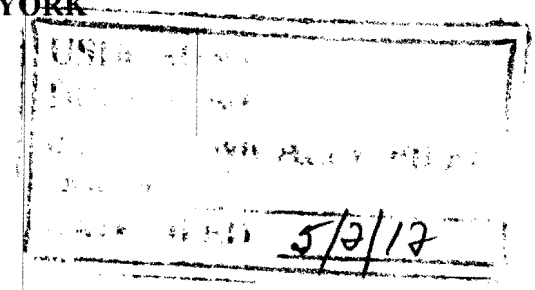
IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK



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

Plaintiffs' motion is granted.

SO ORDERED
5/2/12
THEODORE H. KATZ
UNITED STATES MAGISTRATE JUDGE

PLAINTIFFS' MOTION TO STRIKE NON-RECORD MATERIAL

Plaintiffs respectfully move to strike an industry statement relied on by FDA in its reply brief in support of its motion for summary judgment. *See* Reply Mem. in Supp. of the Government's Mot. for Summ. J. on Pls.' First Supplemental Compl. 13, Apr. 16, 2012 (Dkt. 77). The statement was issued last week by the Animal Health Institute (AHI), a trade association representing manufacturers of animal drugs. *See* Ex. F to Third Decl. of Amy A. Barcelo (3d Barcelo Decl.), Apr. 16, 2012 (Dkt. 78-6). It is not part of the administrative record that was before FDA when the agency denied plaintiffs' citizen petitions in November 2011.

Because this Court's review is limited to the record before FDA at the time it denied the petitions, the Court should strike the AHI statement.

ARGUMENT

"It is a widely accepted principle of administrative law that the courts base their review of an agency's actions on the materials that were before the agency at the time its decision was made." *IMS, P.C. v. Alvarez*, 129 F.3d 618, 623 (D.C. Cir. 1997); *see Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984) ("If a court is to review an agency's action fairly, it should have before it neither more nor less information than did the agency *when it made its decision*." (emphasis added)). Courts do not consider material that postdates the agency's decision because to do so "risks . . . requiring administrators to be prescient or allowing them to take advantage of post hoc rationalizations." *Walter O. Boswell Mem'l Hosp.*, 749 F.2d at 792; *see id.* at 793-94 (noting that the court had struck the portion of an amicus brief discussing a study performed after the agency had made its decision).

As a basis for denying plaintiffs' citizen petitions, FDA asserted its faith in the voluntary cooperation of industry in implementing the agency's Draft Guidance No. 209, which discourages "injudicious" uses of medically important antibiotics in livestock. *See* FDA, Draft Guidance No. 209, at 16-17 (2010) (Administrative Record, at FDA 182-83); Ex. A to Decl. of Mitchell S. Bernard (Bernard Decl.) 4, Feb. 21, 2012 (Dkt. 59-1); Bernard Decl. Ex. B, at 3-4 (Dkt. 59-2). Having failed to identify any evidence in the record that supports its professed confidence in voluntary measures, FDA cannot now rely on AHI's April 11, 2012 statement, issued more than five months after the agency denied the petitions. Although the statement provides little support for FDA's position—it expresses only vague agreement with FDA's "direction" on antibiotics in livestock, while maintaining that "there are details that must be addressed to make this approach practical and workable," *see* 3d Barcelo Decl. Ex. F, at 1—

plaintiffs object to FDA's reliance on material that is not part of the administrative record. This Court should strike the AHI statement in its entirety.

The same reasoning applies to the three documents that FDA published last week and has submitted twice to this Court—once by letter, dated April 11, 2012, and a second time with its reply brief, filed on April 16, 2012. *See* 3d Barcelo Decl. Exs. A, B & C (Dkts. 78-1 to 78-3). These documents—Guidance No. 209, Draft Guidance No. 213, and draft proposed revisions to FDA's Veterinary Feed Directive regulation—are not part of the administrative record on which FDA denied the citizen petitions. To the extent that FDA now relies on them to justify its denials of the petitions, the Court should disregard them.

CONCLUSION

To ensure that it is reviewing FDA's denials of the citizen petitions based on the same information that was before the agency when it issued the denials, this Court should strike the April 11, 2012 statement by AHI (Dkt. 78-6).

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Dated: April 18, 2012

Respectfully submitted,

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