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 COMPLETE THE ADMINISTRATIVE RECORD

Plaintiffs respectfully move for an order completing the administrative record with three documents that were before the U.S. Food and Drug Administration (FDA) when it denied plaintiffs' citizen petitions. The three documents are industry comments on FDA's Draft Guidance No. 209, which discourages "injudicious" uses of medically important antibiotics in livestock. *See* FDA, Draft Guidance No. 209, at 16-17 (2010) (Administrative Record, at FDA 182-83); Exs. C, D & E to Decl. of Mitchell S. Bernard (Bernard Decl.), Feb. 21, 2012 (Dkts. 59-3, 59-4, 59-5).

As a basis for denying plaintiffs' citizen petitions, FDA asserted its faith in the voluntary cooperation of industry in implementing Draft Guidance No. 209. The industry comments bear directly on plaintiffs' legal claims and are properly part of the administrative record under the Administrative Procedure Act's "whole record" review standard. 5 U.S.C. § 706.

ARGUMENT

In determining whether the petition denials were "arbitrary, capricious, . . . or otherwise not in accordance with law," this Court must "review the whole record or those parts of it cited by a party." 5 U.S.C. § 706; *see Dopico v. Goldschmidt*, 687 F.2d 644, 654 (2d Cir. 1982); *Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984). The "'complete administrative record consists of all documents and materials *directly or indirectly* considered by the agency.'" *Merritt Parkway Conservancy v. Mineta*, 424 F. Supp. 2d 396, 403 (D. Conn. 2006) (quoting *Bar MK Ranches v. Yuetter*, 994 F.2d 735, 739 (10th Cir. 1993)) (emphasis added); *see Dopico*, 687 F.2d at 654 (holding that the administrative record encompasses the agency's "informational base" at time of the disputed decision); *Walter O. Boswell Mem'l Hosp.*, 749 F.2d at 792 (holding that a reviewing court "should have before it neither more nor less information than did the agency when it made its decision"). Courts "must protect the public interest in ensuring that agencies do not ignore inconvenient information or skew the record . . . by excluding pertinent but unfavorable information." *Merritt Parkway*, 424 F. Supp. 2d at 403 (internal quotation marks omitted).

The three industry comments filed as Exhibits C, D, and E to the Bernard Declaration fall well within the scope of FDA's administrative record for the petition denials. The comments were submitted to FDA in August 2010, in response to the agency's request for comments on Draft Guidance No. 209. They are signed by the Animal Health Institute, the national trade

association representing manufacturers of animal drugs; Alpharma, an animal drug manufacturer; and the American Farm Bureau Federation. FDA posted the comments to its public docket for Draft Guidance No. 209 at www.regulations.gov.

In denying the petitions in November 2011, FDA proposed to address the problem of antibiotic resistance by "work[ing] with [drug] sponsors who approach FDA and are interested in working cooperatively" "to implement the principles recommended in draft [Guidance] #209." *See* Bernard Decl. Ex. A, at 4 (Dkt. 59-1). The agency asserted that "[b]ased on feedback this Agency has received following the issuance of draft [Guidance] #209, FDA believes that the animal pharmaceutical industry is generally responsive to working cooperatively with the Agency." *Id.* The Government included Draft Guidance No. 209 in the administrative record it filed with this Court, but it omitted the industry comments. *See* Administrative Record, at FDA 167-85. The comments question whether the use of antibiotics to promote animal production poses any threat at all to human health. *See* Bernard Decl. Ex. C, at 1-2; *id.* Ex. D, at 1-2; *id.* Ex. E, at 3. Plaintiffs have argued that, even if FDA's reliance on voluntary measures were a legitimate statutory basis for denying the petitions, the agency has offered no evidence to support its professed confidence in the efficacy of voluntary measures, and in fact there is no reason to believe that such measures will be effective. The industry comments on Draft Guidance No. 209 are probative of the question whether the evidence that was before the agency supports FDA's stated rationale for denying the petitions.

CONCLUSION

To ensure that it can review the petition denials on the "whole record," 5 U.S.C. § 706, this Court should grant plaintiffs' motion and order the administrative record completed with the documents filed as Exhibits C, D, and E to the Bernard Declaration.

Dated: April 2, 2012

Respectfully submitted,

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