UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PUBLIC EMPLOYEES FOR ENVIRONMENTAL RESPONSIBILITY, 2000 P Street, NW, Suite 240 Washington, D.C. 20036	)	
Plaintiff,	)	
v.	)	
	)	Civil Action #
U.S. FOOD AND DRUG ADMINISTRATION, 10903 New Hampshire Avenue Silver Spring, MD 20993	)	
	)	**COMPLAINT**
Defendant.	)	

PRELIMINARY STATEMENT

1. This action is brought under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, *et seq.*, as amended, in order to compel the U.S. Food and Drug Administration ("FDA" or "the Agency") to disclose records wrongfully withheld after two separate FOIA requests from Plaintiff.

2. FOIA requires that federal agencies respond to public requests for documents, including files maintained electronically, in order to increase public understanding of the workings of government and access to government information.

3. Plaintiff Public Employees for Environmental Responsibility ("PEER") is a non-profit organization with tax-exempt status dedicated to research and public education concerning the activities and operations of the federal government.

4. Plaintiff's first request ("Categorical Exclusions Request") sought the subject documents to clarify and document the FDA's use of categorical exclusions to avoid having to conduct an

environmental assessment or environmental impact statement under the National Environmental Policy Act ("NEPA") in the approval of animal pharmaceuticals for sub-therapeutic uses.

5. Plaintiff's second request ("Voluntary Cooperation Request") sought the subject documents to clarify and document the basis of the FDA's decision—published in the Federal Register at 76 Fed. Reg. 79,697 (Dec. 22, 2011)—to withdraw two notices and opportunity for a hearing regarding potential revocation of FDA approval for certain uses of penicillin and tetracyclines in animal feed due to purportedly having achieved the agreement of the animal pharmaceutical industry to work voluntarily with the Agency on those issues.

6. Both of these requests serve to help the public understand the policies FDA uses to regulate animal pharmaceuticals—an important public health issue as these drugs are known to leach from feeding operations into surface and groundwater, the effects of which on humans and the environment are only just beginning to be studied. Moreover, the public trust is well served by knowing the extent to which FDA implements, or fails to implement, its key statutory responsibilities.

7. Plaintiff's Categorical Exclusions Request was dated and submitted to FDA November 4, 2011. In two separate letters, Plaintiff received from FDA an acknowledgement of and an approval of the fee waiver for the Categorical Exclusions Request. To date, Plaintiff has not received any documents responsive to this request.

8. Plaintiff's Voluntary Cooperation Request was dated and submitted January 4, 2012. In two separate letters, Plaintiff received an acknowledgement of and approximately 90 pages of documents unresponsive to the Voluntary Cooperation Request. Plaintiff believes this unresponsive reply is a constructive denial and appealed to the Agency on February 13, 2012. The Agency has not made a determination as to Plaintiff's appeal within the statutory deadline

and Plaintiff has received no other documents relating to this request.

9. FDA's conduct is arbitrary and capricious and amounts to a denial of Plaintiff's FOIA requests. FDA's conduct frustrates Plaintiff's efforts to educate the public regarding FDA's efforts to study and protect the public from pollution resulting from animal pharmaceuticals and overall ability to meet its statutory responsibilities.

10. Plaintiff seeks a court order requiring FDA to immediately produce the documents sought in both the Categorical Exclusions and Voluntary Cooperation Requests, as well as other appropriate relief.

JURISDICTION AND VENUE

11. This Court has jurisdiction over this action under the Freedom of Information Act, 5 U.S.C. § 552(a)(4)(B). This Court also has jurisdiction over this action under 28 U.S.C. § 1331 (federal question jurisdiction).

12. This Court has the authority to grant declaratory relief pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*

13. This Court is a proper venue because Plaintiff resides in this district. 28 U.S.C. § 1391(e)(1)(C) (where defendant is the government or a government agent, a civil action may be brought in the district where the plaintiff resides if there is no real property at issue). Venue is also proper under 5 U.S.C. § 552(a)(4)(B).

14. This Court has the authority to award costs and attorneys' fees under 28 U.S.C. § 2414 and 5 U.S.C. § 552(a)(4)(E).

PARTIES

15. Plaintiff PEER is a non-profit public interest organization, with its main office located Washington, D.C., and field offices located in California, Colorado, Florida, Massachusetts, New Mexico, New Jersey, and Tennessee.

16. PEER is not a commercial enterprise for purposes of the fee waiver provisions of FOIA. *See* 5 U.S.C. § 552(a)(4)(A)(iii). Among other public interest projects, PEER engages in advocacy, research, education, and litigation relating to the promotion of public understanding and debate concerning key current public policy issues, focusing on the environment, public lands and natural resource management, public funding of environmental and natural resource agencies, and ethics in government.

17. Informing the public about these important public policy issues is central to PEER's mission. PEER educates and informs the public through news releases to the media, PEER's web site, www.peer.org, which draws between 1,000 and 10,000 viewers per day, and PEER's newsletter which has a circulation of approximately 20,000, including 1,500 environmental journalists.

18. Defendant FDA is an agency of the United States as defined by 5 U.S.C. § 552(f)(1), and is charged with the duty to provide public access to documents in its possession consistent with the requirements of the FOIA and is denying Plaintiff access to its records in contravention of federal law.

FACTS

November 4, 2011 Categorical Exclusions Request, FOIA # 2011-8119

19. Plaintiff's Categorical Exclusions Request was dated and submitted to the Agency November 4, 2011.

20. Plaintiff's Categorical Exclusions Request sought the following information regarding FDA's use of categorical exclusions during approval pursuant to 21 C.F.R. § 25.33 of animal pharmaceuticals:

> The final approval documents pertaining to the issuance of categorical exclusions given for all animal drugs approved for sub-therapeutic uses where the Agency has invoked the following categorical exclusion to approve its use:
>
> 1. 21 C.F.R. §25.33 (a)(1)–Animal drugs to be marketed under the same conditions of approval as a previously approved animal drug;
>
> 2. 21 C.F.R. § 25.33(a)(7)–Approval of a drug for use in animal feeds if such drug has been approved under § 514.2 or § 514.9 of this chapter for other uses;
>
> 3. 21 C.F.R. § 25.33(d)(1)–Drugs intended for use in nonfood animals;
>
> 4. 21 C.F.R. § 25.33(d)(3)–Nonsystemic topical animal drugs. Please note that PEER only requests the final approval documents for drugs that have been categorically excluded under this subpart that are topical drugs, not ophthalmic drugs; and
>
> 5. 21 C.F.R. §25.33(d)(4)–Drugs for minor species, including wildlife and endangered species, when the drug has been previously approved for use in another or the same species where similar management practices are used.

21. Plaintiff received an acknowledgement of the Categorical Exclusions Request from FDA dated November 7, 2011, whereby this request was designated # 2011-8119.

22. Plaintiff received an approval of the fee waiver for the Categorical Exclusions Request dated November 15, 2011.

23. To date, Plaintiff has received no documents responsive to this request. In good faith, Plaintiff has afforded FDA ample time beyond that which is legally required to respond to the Categorical Exclusions FOIA request; it has been over six months since the FDA acknowledged

Plaintiff's Categorical Exclusions FOIA request.

24. Plaintiff has fully exhausted its administrative remedies for the Categorical Exclusions Request. Administrative remedies are deemed exhausted whenever an agency fails to comply with the applicable time limits, as stated by 5 U.S.C. § 552(a)(6)(C). Plaintiff now turns to this Court to enforce the remedies and public access to agency records guaranteed by FOIA.

January 4, 2012 Voluntary Cooperation Request, FOIA # 2012-106

25. Plaintiff's Voluntary Cooperation Request was dated and submitted to the Agency January 4, 2012.

26. Plaintiff's Voluntary Cooperation Request sought the following information regarding FDA's confidence in voluntary compliance with the judicious use of antibiotics by the animal pharmaceutical industry:

> 1. All documents, analyses, reports, or communications (both internal and external to FDA) which support FDA's stated belied[sic – belief] that "the animal pharmaceutical industry is generally responsive to the prospect of working cooperatively with the Agency to accomplish the principles recommended in draft GFI #209";
>
> 2. Any documents reflecting past success that FDA has achieved in inducing the animal pharmaceutical industry to curb the use of antimicrobial drugs;
>
> 3. All documents reflecting or describing the specific FDA plan to monitor this voluntary compliance following this *Federal Register* notice;
>
> 4. All communications between FDA and the Office of the Secretary of Health & Human Services and/or the White House concerning the subject matter of this *Federal Register* notice (this item is limited to any such documents generated from 1/1/10 to present) and
>
> 5. All decision documents supporting this *Federal Register* notice, including any which detail why withdrawal proceedings are not warranted at this time and what circumstances will be

required before withdrawal proceedings become warranted.

27. Plaintiff received an acknowledgement for the Voluntary Cooperation Request from the Agency dated January 6, 2012, whereby this request was designated # 2012-106.

28. Plaintiff received a package dated January 8, 2012, with approximately 90 pages of documents unresponsive to Plaintiff's request.

29. Pages 1 through 29 of the Agency's production were not responsive to the request as they are a submission from Keep Antibiotics Working (KAW), a coalition of environmental, animal welfare, and health groups that claim that the FDA is not doing enough to limit the use of antibiotics in feed animals.

30. Pages 30 through 42 of the Agency's production were not responsive to the request as they are notes regarding attendees at a meeting of the Animal Agriculture Coalition and are not indicative of any compliance.

31. Pages 43 through 49 of the Agency's production were not responsive to the request as they are a copy of the Deputy Commissioner of the FDA's testimony for the House describing why over-use of antibiotics is a problem. This is also not evidence of any type of compliance in the industry.

32. Pages 50 through 70 of the Agency's production were not responsive to the request as they are notes and attachments regarding a meeting between representatives of the FDA, the Translational Genomics Research Institute, and the Pew Charitable Trusts about a ban in Denmark on the use of antibiotics as a growth enhancer. The attachment included duplicates of documents described above.

33. Pages 71 through 73 of the Agency's production were not responsive to the request as they are a duplicate copy of a letter from the Pew Charitable Trusts given to PEER as an

attachment in the previous document.

34. Pages 74 through 76 of the Agency's production were not responsive to the request as they are another letter from KAW concerning the standard that FDA uses to withdraw use of an antibiotic.

35. Pages 77 through 89 of the Agency's production were not responsive to the request as they are an e-mail from KAW attaching a letter to Senator Kennedy responding to questions from Senators.

36. Pages 90 through 91 of the Agency's production were not responsive to the request as they are an email from Pew to FDA attaching a *New York Times* editorial.

37. None of the documents described in paragraphs 29 through 36 above are evidence of voluntary compliance with judicious use of antibiotics in animal feed or in any but the most attenuated fashion responsive to Plaintiff's FOIA request.

38. Plaintiff believes this reply is unresponsive to its Voluntary Cooperation Request and is a constructive denial of Plaintiff's request. Plaintiff filed an appeal regarding this constructive denial on February 13, 2012.

39. The Agency has not responded to Plaintiff's appeal within the twenty-day statutory deadline to make a determination on a FOIA appeal, 5 U.S.C. § 552(a)(6)(A)(ii); over three months have passed since the deadline, and Plaintiff has received no answer regarding the appeal and no documents responsive to Plaintiff's request.

40. Plaintiff has fully exhausted its administrative remedies as required by 5 U.S.C. § 552(a)(6)(C) for the Voluntary Cooperation Request, and now turns to this Court to enforce the remedies and public access to agency records guaranteed by FOIA.

CAUSES OF ACTION

I. Count 1: Violation of the Freedom of Information Act

41. Plaintiff incorporates the allegations in paragraphs 1 through 40.

42. FDA's failure to disclose the requested documents or to provide the requested information in FOIA Request No. 2011-8819 and FOIA Request No. 2012-106 is a violation of FOIA, 5 U.S.C. § 552, and the Agency's own regulations promulgated thereunder.

43. FDA's wrongful withholding of the requested documents in FOIA Request No. 2011-8819 is a violation of FOIA, 5 U.S.C. § 552, and the Agency's own regulations promulgated thereunder.

44. FDA's production of documents unresponsive to FOIA Request No. 2012-106 is a constructive denial and wrongful withholding of documents in violation of FOIA, 5 U.S.C. § 552, and the Agency's own regulations promulgated thereunder.

RELIEF REQUESTED

WHEREFORE, Plaintiff respectfully requests and prays that this Court:

i. Enter an Order declaring that FDA has wrongfully withheld the requested Agency records;

ii. Issue a permanent injunction directing FDA to disclose to Plaintiff all wrongfully withheld documents;

iii. Maintain jurisdiction over this action until FDA is in compliance with FOIA, APA and every order of this Court;

iv. Award Plaintiff its attorney fees and costs pursuant to 5 U.S.C. § 552(a)(4)(E); and

v. Grant such additional and further relief to which Plaintiff may be entitled.

Dated: June 29, 2012

Respectfully submitted,

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