UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

GOVERNMENT ACCOUNTABILITY PROJECT **1612 K Street, NW, Suite 1100** **Washington, DC 20006** **Plaintiff,** **v.** **U.S. FOOD AND DRUG ADMINISTRATION** **5600 Fishers Lane** **Rockville, MD 20857** **Defendant.**	)	**Case No. 12-1954**

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. This action is brought under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 *et seq.*, to compel the release of records in the possession of the U.S. Food and Drug Administration containing information requested by the non-profit Government Accountability Project ("GAP").

Jurisdiction and Venue

2. This Court has subject matter jurisdiction over this action and personal jurisdiction over the parties pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331. Venue is proper in this district under 5 U.S.C. § 552(a)(4)(B).

Parties

3. Plaintiff Government Accountability Project ("GAP") is a non-profit organization located in Washington, D.C. GAP's activities include supporting and litigating on behalf of

whistleblowers in the federal government and in the private sector, and leading campaigns to enact and strengthen whistleblower protection laws domestically and internationally. GAP's program areas include the Food Integrity Campaign. The mission and long term objective of GAP's Food Integrity Campaign is to enhance overall food integrity by facilitating truth-telling and transparency. GAP's Food Integrity Campaign seeks to accomplish this mission by strategically working to alter the relationship of power between the food industry and consumers, protecting the rights of those who speak out against practices that compromise food integrity, and empowering industry whistleblowers and citizen activists.

4. Defendant U.S. Food and Drug Administration ("FDA") is an agency of the United States government, and is responsible for the enforcement of the Animal Drug and User Fee Act. Defendant FDA is an Operating Division of the U.S. Department of Health and Human Services. Defendant FDA has possession and control of the records requested by GAP.

Statutory Framework

5. The Freedom of Information Act requires agencies of the federal government, upon request, to release information to the public, unless the agency demonstrates that one of the nine enumerated statutory exemptions applies. 5 U.S.C. §§ 552(a), (b).

6. Exemption 4 of the Freedom of Information Act allows an agency to withhold "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4).

7. The Animal Drug User Fee Act, as amended in 2008, requires sponsors of certain animal drugs containing antimicrobial active ingredients to submit a report each year to the

Secretary of Health and Human Services specifying the amount of each antimicrobial active ingredient sold or distributed for use in food-producing animals. 21 U.S.C. § 360b(l)(3). The Animal Drug User Fee Act requires sponsors to report these amounts for each "container size, strength, and dosage form" in which the drug is sold or distributed. 21 U.S.C. § 360b(l)(3)(B)(i). The Animal Drug User Fee Act also requires sponsors to report, for each dosage form, the target animals that are specified on the approved label of the product. 21 U.S.C. § 360b(l)(3)(B)(iii). The Secretary is required to publish annual summaries of this information, with the amounts of antimicrobial active ingredient aggregated by antimicrobial class. 21 U.S.C. § 360b(l)(3)(E). Where an antimicrobial class has fewer than three distinct sponsors of drugs containing the antimicrobial active ingredient, the Animal Drug and User Fee Act directs the Secretary to exclude the information concerning that class from its annual summary. 21 U.S.C. § 360b(l)(3)(E)(i).

Facts

8. On February 10, 2011, GAP submitted a Freedom of Information Act request to the FDA requesting the following information: (1) printed copies of all educational and outreach materials that FDA has prepared in order to inform and assist antimicrobial drug sponsors in fulfilling their duty to report the amount of antimicrobial active ingredient in their drugs that have been sold or distributed for use in food-producing animals pursuant to Sec. 105 of the Animal Drug User Fee Amendments of (2008); (2) FDA's data for use of anti-microbial drugs in food-producing animals in 2009 as broken down by container size, strength, and dosage form; and (3) FDA's data for use of anti-microbial drugs in food-producing animals in 2009 as broken down by class of animal.

9. In its February 10, 2011 request, GAP included a request for a waiver of applicable fees.

10. On or about February 15, 2011, Frederick J. Sadler, Director, FDA Division of Freedom of Information, mailed a letter to GAP in which Mr. Sadler stated that the FDA had granted GAP's request for a waiver of fees.

11. On May 4, 2011, FDA responded to GAP's request with copies of materials responsive to the first part of GAP's request, which sought printed copies of all educational and outreach materials that FDA has prepared in order to inform and assist antimicrobial drug sponsors in fulfilling their duty to report the amount of antimicrobial active ingredient in their drugs that have been sold or distributed for use in food-producing animals pursuant to Sec. 105 of the Animal Drug User Fee Amendments of (2008).

12. On May 24, 2011, FDA FOIA Officer Sandra McGeehan informed GAP via a telephone call that FDA was still reviewing parts (2) and (3) of GAP's request for information.

13. On June 9, 2011, GAP received a letter from Frederick J. Sadler, Director, FDA Division of Freedom of Information, in which Mr. Sadler indicated that FDA had denied GAP's request to release records described in parts (2) and (3) of its FOIA request on the basis that those records are exempt from disclosure under Exemption 4 of the Freedom of Information Act.

14. On July 11, 2011, GAP submitted a letter to the Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services appealing the FDA's decision to deny parts (2) and (3) of GAP's Freedom of Information Act request. In this letter, GAP

recounted the relevant events, argued that the FDA's decision to withhold responsive records under Exemption 4 of the Freedom of Information Act was improper, and requested that the FDA reverse its decision to deny parts (2) and (3) of GAP's request.

15. On July 3, 2012, having not received a response to its July 11, 2011 administrative appeal letter, GAP contacted the U.S. Department of Health and Human Service's FOIA Office in order to request the status of its administrative appeal. The official who answered the telephone in that office directed GAP to contact the Public Health Service Freedom of Information Officer to inquire about the status of its administrative appeal.

16. On that same date, July 3, 2012, GAP contacted the Public Health Service Freedom of Information Office, and spoke with an official in that office, who stated that GAP could expect to receive a response to its administrative appeal by the end of August.

17. On July 5, 2012, GAP received a message from Mary McCarthy, who indicated that she was responsible for processing GAP's administrative appeal, and sought to speak with GAP regarding the scope of its request.

18. Later that same day, July 5, 2012, GAP contacted Ms. McCarthy, who asked whether GAP was seeking specific data on sales or distribution of drugs by individual sponsors, or whether GAP was seeking aggregated data. GAP informed Ms. McCarthy that it would need to call her back at a later time regarding her question.

19. On July 11, 2012, GAP placed a call to Ms. McCarthy, and left a message asking for her to return the call as soon as possible.

20. On July 16, 2012 GAP received a message from Ms. McCarthy, in which she stated that she had been on vacation during the previous week, but was not back in her office.

21. Later that day, July 16, 2012, GAP contacted Ms. McCarthy via telephone in order to answer the question she had asked on July 5th. GAP informed Ms. McCarthy that the information being sought was aggregated data concerning the amount of antimicrobial active ingredient sold for each class of antimicrobial drugs, rather than data concerning sales or distribution by each individual sponsor, broken down by container size, strength, dosage form, and class of animal. Ms. McCarthy suggested that submitting an explanation in writing might help her to further understand exactly what GAP is seeking, and provided GAP with the email address for her office.

22. GAP consulted with persons having subject matter expertise for the purpose of preparing a written explanation and chart to illustrate the information being sought in its request, and, on July 30, 2012, contacted Ms. McCarthy via telephone to let her know that it would be submitting the written explanation and illustration via email that day.

23. During the call with Ms. McCarthy on July 30, 2012, Ms. McCarthy informed GAP that she had decided to uphold the FDA's initial decision to deny parts (2) and (3) of GAP's FOIA request. GAP reminded Ms. McCarthy that she had expressed some confusion regarding the scope of GAP's request and that a written explanation might help her to understand exactly what information was being sought, and that GAP had prepared a written explanation to assist her. Ms. McCarthy responded, referring to GAP's request, that she had "had to get it off [her]

desk." She stated that she was not sure how long it would take for GAP to receive the written letter denying its administrative appeal.

24. On or about September 19, 2012, William H. Hall, Director, News Division, Office of the Assistant Secretary for Public Affairs, mailed a letter to GAP upholding the FDA's initial decision to deny parts (2) and (3) of GAP's FOIA request.

25. In the September 19, 2012 letter, Mr. Hall stated that the information sought by GAP in parts (2) and (3) was being withheld pursuant to Exemption 4 of the Freedom of Information Act.

26. On information and belief, the information sought by GAP is reflected in studies and other records in the possession and control of the FDA.

27. The information sought by GAP does not concern, and disclosure of the information would not reveal, any commercially valuable plan, formula, process, or device used for the making, preparing, compounding, or processing of any trade commodities.

28. The information sought by GAP was not "obtained from a person" by the FDA as that phrase is used in 5 U.S.C. § 552(b)(4).

29. The information sought by GAP is not "financial information" as that term is used in 5 U.S.C. § 552(b)(4).

30. The information sought by GAP is not provided to the FDA voluntarily.

31. Disclosure of the information sought by GAP is not likely to impair the government's ability to obtain the same or similar information in the future.

32. Disclosure of the information sought by GAP is not likely to cause substantial harm to the competitive position of any manufacturers of drugs containing the antimicrobial active ingredients to which the information pertains.

Count I
Violation of the Freedom of Information Act: Wrongful Withholding of Agency Records

33. Paragraphs 1-32 above are incorporated herein by reference as if set forth fully herein.

34. GAP has exhausted the applicable administrative remedies with respect to GAP's Freedom of Information Act request.

35. FDA has wrongfully invoked Exemption 4 of the Freedom of Information Act and withheld responsive records in its possession and control to which GAP is entitled under the Freedom of Information Act.

36. GAP is entitled to injunctive relief compelling the disclosure of the requested information.

Prayer for Relief

WHEREFORE, Plaintiff prays that this Court:

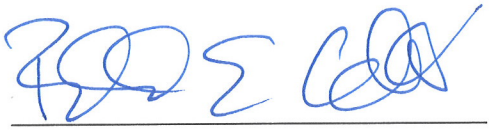
(1) Declare that Defendant's withholding of the requested information is unlawful;

(2) Order Defendant FDA to make the requested information available to Plaintiff GAP within ten (10) working days.

(3) Award Plaintiff GAP its costs and reasonable attorneys' fees incurred in this action pursuant to 5 U.S.C. § 552(a)(4)(E); and

(4) Grant any further relief as the Court may deem just and proper.

Respectfully Submitted,



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