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, Maryland 20857** **Defendant.**	)	Civ. No. 1:12-cv-01954 (KBJ)

PLAINTIFF'S RESPONSE TO
DEFENDANT FDA's STATEMENT OF MATERIAL FACTS

1. Section 105 of the Animal Drug and User Fee Amendments of 2008 ("ADUFA"), 110 P. L. 316, 122 Stat. 3509, codified at 21 U.S.C. § 360b(l)(3), requires sponsors of new animal drugs that contain an antimicrobial active ingredient to submit annual reports to FDA on "the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals." 21 U.S.C. § 360b(l)(3)(A).

PLAINTIFF'S RESPONSE: Denied. This is a statement of law, not a material fact.

2. By letter dated February 10, 2011, Plaintiff requested under the FOIA,

> (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. Declaration of Gorka Garcia-Malene ("Garcia-Malene Decl."), Ex. A, ¶ 5; Pl.'s Stmt. of Mat. Facts As to Which There Is No Genuine Issue ("Pl.'s SOF"), ECF No. 9-3, ¶ 2.

PLAINTIFF'S RESPONSE: Admitted.

3. FDA responded to the first part of Plaintiff's FOIA request on May 4, 2011, and FDA denied the remaining parts of Plaintiff's request because they were exempt from disclosure. Garcia-Malene Decl., Ex. A, ¶¶ 6–7; Pl.'s SOF, ECF No. 9-3, ¶ 3.

PLAINTIFF'S RESPONSE: Admitted in part. However, the Plaintiff denies that information responsive to its request was exempt from disclosure.

4. Plaintiff subsequently modified its FOIA request with respect to the second and third parts of its request, to seek data collected pursuant to 21 U.S.C. § 360b(l)(3) containing the aggregated amount of antimicrobials sold or distribution for use in food producing animals in 2009, broken down by container size, strength, dosage form, and class of animal, for each antimicrobial class. See Compl. ¶ 21; Joint Status Report, ECF. No. 5, ¶ 1; Garcia-Malene Decl., Ex. A, ¶ 8; Pl.'s SOF, ECF No. 9-3, ¶ 4.

PLAINTIFF'S RESPONSE: Admitted.

5. FDA conducted a search based on Plaintiff's modified request and located two documents partially responsive to Plaintiff's modified request ("Document 1" and "Document 2"). Garcia-Malene Decl., Ex. A, ¶ 9. See also Pl.'s SOF, ECF No. 9-3, ¶ 5.

PLAINTIFF'S RESPONSE: Admitted.

6. FDA produced Document 1 and Document 2 with redactions. Garcia-Malene Decl., Ex. A, ¶ 9; Pl.'s SOF, ECF No. 9-3, ¶ 6.

PLAINTIFF'S RESPONSE: Admitted.

7. When FDA originally produced Document 2 to Plaintiff, FDA stated that Document 2 was a draft summary of certain aggregated data and that the accuracy of the data had not been verified. Consent Motion to Stay Litigation ("Consent Motion"), ECF No. 19, at 1; Garcia-Malene Decl., Ex. A, ¶ 13.

PLAINTIFF'S RESPONSE: Admitted.

8. After the parties briefed cross-motions for summary judgment, FDA determined that some of the 2009 sales and distribution numbers included in Document 2 were not accurate and updated this information in a separate document ("Revised Document 2"). See Consent Motion, ECF No. 19; Notice of Filing, ECF No. 21; Garcia-Malene Decl., Ex. A, ¶¶ 13–14; Revised Document 2, Ex. A(4).

PLAINTIFF'S RESPONSE: Admitted.

9. Plaintiff does not challenge the scope or adequacy of FDA's search. See Joint Status Report, ECF No. 6, at 2; Mem. in Opp'n. to Def.'s Mot. for Summ. J. and in Supp. of Pl.'s Mot. for Summ. J. ("Pl.'s Mem."), ECF No. 9-1, at 2. Plaintiff also does not challenge the redactions made to Document 1. Pl.'s Mem., ECF No. 9-1, at 2. Furthermore, Document 2 (as originally released) is no longer at issue. See Joint Status Report, ECF No. 22, at 1; Garcia-Malene Decl., Ex. A, ¶ 15.

PLAINTIFF'S RESPONSE: Admitted.

10. Plaintiff objects to the redactions to Revised Document 2. Garcia-Malene Decl., Ex. A, ¶ 15.

PLAINTIFF'S RESPONSE: Admitted.

11. The information redacted in Revised Document 2 was obtained from sponsors of new animal drug applications. These sponsors are corporations and companies. Garcia-Malene Decl. ¶ 28; Declaration of Thomas Elam, President of FarmEcon LLC ("Elam Decl."), Ex. C, ¶¶ 10–11; Declaration of Jeet Uppal, Group Director of Global Market Research at Zoetis, Inc. ("Uppal Decl."), Ex. D, ¶¶ 4–6; Declaration of Warren M. Harper, Senior Vice President of Global Marketing at Phibro Animal Health Corporation ("Harper Decl."), Ex. E, ¶ 10; Declaration of Michael Mlodzik, Manager of Pharmaceutical Regulatory Affairs at Boehringer-Ingelheim Vetmedica, Inc. ("Mlodzik Decl."), Ex. H, ¶ 8.

PLAINTIFF'S RESPONSE: Admitted.

12. The information redacted in Revised Document 2 is sales and distribution data that is confidential commercial and financial information. See, e.g., Garcia-Malene Decl. ¶¶ 17, 35–39; Uppal Decl., Ex. D, ¶¶ 8–10; Harper Decl., Ex. E, ¶ 11; Declaration of Scott Bormann, Vice President, North America at Intervet, Inc. ("Bormann Decl."), Ex. F, ¶ 7; Declaration of Cathy Martin, Chief Marketing Officer, North America, at Elanco, a division of Eli Lilly and Company ("Martin Decl."), Ex. G, ¶ 10; Mlodzik Decl., Ex. H, ¶¶ 25–26; Declaration of Kelly W. Beers, Regulatory Manager at Huvepharma, Inc. ("Beers Decl."), Ex. I, ¶ 8; Declaration of Robert Zolynas, Vice President for Research and Development at Bayer HealthCare LLC ("Zolynas Decl."), Ex. J, ¶ 7; Declaration of S. Lee Whaley, Director of Regulatory Affairs at Norbrook, Inc. ("Whaley Decl."), Ex. K, ¶¶ 5–6.

PLAINTIFF'S RESPONSE: Admitted that information redacted in Revised Document 2 is sales and distribution data is commercial and financial in nature. Plaintiff denies that the redacted data in Revised Document 2 is confidential and precluded from release under either FOIA Exemptions 3 or 4. "[F]or the government to preclude disclosure based on a competitive injury

claim, it must prove that the submitters '(1) actually face competition, and (2) substantial competitive injury would likely result from disclosure.'" *Niagara Mohawk,* 169 F.3d 18. For the many reasons stated in Plaintiff's Memorandum, FDA has not met its burden to establish that the information in dispute is "confidential" as that term is interpreted in Exemption 4 case law.

13. FDA redacted three types of information from Revised Document 2: (a) all of the individualized sales and distribution data (i.e., where the data is from one distinct sponsor), (b) all of the aggregated sales and distribution data of two distinct sponsors, and (c) the aggregated sales and distribution data of three or more distinct sponsors that would reveal the aggregated sales and distribution data of one or two distinct sponsors if released. Garcia-Malene Decl., Ex. A, ¶ 26.

PLAINTIFF'S RESPONSE: Admitted.

14. The information redacted from Revised Document 2 is customarily not disclosed to the public. See, e.g., Elam Decl., Ex. C, ¶ 43; Uppal Decl., Ex. D, ¶¶ 8–10, 23; Harper Decl., Ex. E, ¶¶ 11–14; Bormann Decl., Ex. F, ¶¶ 8–10; Martin Decl., Ex. G, ¶¶ 8–9, 22; Mlodzik Decl., Ex. H, ¶¶ 10–15; Beers Decl., Ex. I, ¶ 8; Zolynas Decl., Ex. J, ¶ 9; Declaration of Douglas Rupp,Vice President, Regulatory Affairs and Operations, at Pharmgate LLC ("Rupp Decl."), Ex. L, ¶ 11.

PLAINTIFF'S RESPONSE: Admitted.

15. There is actual competition in the animal drug industry. See, e.g., Garcia-Malene Decl., Ex. A, ¶ 37; Declaration of Neal Bataller ("Bataller Decl."), Ex. B, ¶ 10–16; Elam Decl., Ex. C, ¶¶ 15–20; Uppal Decl., Ex. D, ¶ 18; Harper Decl., Ex. E, ¶¶ 15–16; Bormann Decl., Ex. F, ¶ 12; Martin Decl., Ex. G, ¶ 11; Mlodzik Decl., Ex. H, ¶¶ 16–17; Beers Decl., Ex. I, ¶ 4; Zolynas Decl., Ex. J,¶ 10; Whaley Decl., Ex. K, ¶ 6; Rupp Decl., Ex. L, ¶ 9.

PLAINTIFF'S RESPONSE: Denied. Defendant FDA's declarants' statements are conclusory, not based upon personal knowledge, and/or are provided without a proper foundation. Fed.R.Civ.P., Rule 56(c)(4); *Niagara Mohawk,* 169 F.3d at 18.

16. There is a likelihood of substantial competitive injury to the drug sponsors that submitted the sales and distribution data redacted in Revised Document 2 if the redacted Case information is made public. See, e.g., Garcia-Malene Decl., Ex. A, ¶ 40; Bataller Decl., Ex. B, ¶ 21; Elam Decl., Ex. C, ¶¶ 21–42; Uppal Decl., Ex. D, ¶¶ 19–25; Harper Decl., Ex. E, ¶¶ 15–26; Bormann Decl., Ex. F, ¶¶ 13–19, 21; Martin Decl., Ex. G, ¶¶ 13–24; Mlodzik Decl., Ex. H, ¶¶ 16–26;

Beers Decl., Ex. I, ¶¶ 4–6; Zolynas Decl., Ex. J, ¶¶ 8, 10; Whaley Decl., Ex. K, ¶ 7; Rupp Decl., Ex. L, ¶ 10.

PLAINTIFF'S RESPONSE: Denied. Even where constructed using a robust set of accurate data points, the predictive accuracy of any model diminished rapidly as the forecast moves further into the future beyond the last known value. The information about 2009 sales would not enable any of these companies to produce an estimate of current sales that would be any more reliable or useful than an intuitive estimate based on in-house data and years of experience working in the industry. P. Ex. 5 ¶ 16. As there are multiple variables in a forecasting model, public disclosure of the redacted information in Document 2 is highly unlikely to cause substantial competitive harm. P. Ex. 1; P. Ex. 5; and P. Ex. 6. Moreover, Defendant FDA's declarants' statements are conclusory, not based upon personal knowledge, and/or are provided without a proper foundation. Fed.R.Civ.P., Rule 56(c)(4); *Niagara Mohawk,* 169 F.3d at 18.

Dated: April 2, 2015

Respectfully Submitted,

/s/ Richard E. Condit

Richard E. Condit
Senior Counsel
DC Bar # 417786
1612 K Street, NW, Suite 1100
Washington, DC 20006
Tel: 202-457-0034, ext. 142
Fax: 202-457-0059
richardc@whistleblower.org