UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

GOVERNMENT ACCOUNTABILITY PROJECT Plaintiff, v. FOOD AND DRUG ADMINISTRATION Defendant.	)	Civ. No. 1:12-cv-01954 (KBJ)

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

The United States Food and Drug Administration ("FDA") respectfully submits this Memorandum of Points and Authorities in Support of its Motion for Summary Judgment.

INTRODUCTION

Plaintiff, Government Accountability Project ("GAP"), filed this action under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, regarding a FOIA request it submitted to FDA by letter dated February 10, 2011, which request Plaintiff modified after filing this lawsuit. FDA located two documents that were partially responsive to Plaintiff's modified request and released them to Plaintiff with redactions. Plaintiff does not challenge the scope or adequacy of FDA's search, or the redactions to one of the documents FDA released. Thus, the only issue for the Court to resolve is whether FDA properly redacted from the second document sales data submitted by sponsors of new animal drug applications ("NADA") pursuant to Section 105 of the Animal Drug User Fee Amendments of 2008 ("ADUFA"), Pub. L. No. 110-316, 122 Stat. 3509, codified at 21 U.S.C. § 360b(l)(3). For the reasons set forth below, these sales data are

exempt from disclosure under Exemptions 3 and 4 of the FOIA. There is no material fact in dispute, and FDA is entitled to judgment as a matter of law.

BACKGROUND

I. Section 105 of ADUFA

Section 105 of ADUFA amended the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360b, to require sponsors of approved applications for animal drugs that contain an antimicrobial active ingredient to submit an annual report to FDA containing "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). The annual report must include, among other things, information on each antimicrobial active ingredient sold or distributed "by container size, strength, and dosage form;" "by quantities distributed domestically and . . . exported;" and "by dosage form, including, for each such dosage form, a listing of the target animals, indications, and production classes . . . ." 21 U.S.C. § 360b(l)(3)(B).

Congress passed Section 105 of ADUFA to improve data collection regarding antimicrobial drug use and to aid FDA in its "continuing analysis of the interactions (including drug resistance), efficacy, and safety of antibiotics approved for use in both humans and food-producing animals." H.R. Rep. No. 110-804, at 14 (2008), reprinted in 2008 U.S.C.C.A.N. 1287, 1295. Congress provided that FDA "may share information reported under this paragraph with the Antimicrobial Resistance Task Force established under [section 319E of the Public Health Service Act]" and "shall make summaries of the information reported under this paragraph publicly available . . . ." 21 U.S.C. § 360b(l)(3)(D), (E).[1] At the same time, Congress mandated

[1] Pursuant to Section 105 of ADUFA, FDA makes public a summary report ("Summary Report") based on the data submitted by sponsors. See 2009 Summary Report, Exhibit ("Ex.") 4 to the Declaration of Gorka Garcia-Malene, FOIA Officer, FDA's Center for Veterinary Medicine ("CVM") (hereafter, "Garcia-Malene Decl."), attached at Ex. A, ¶ 16. Exhibits attached to the

that FDA protect the confidential business information, such as sales data, that Section 105 requires sponsors to submit. In particular, Congress specified that FDA shall report summaries of the sales data "by antimicrobial class" but "no class with fewer than 3 distinct sponsors of approved applications shall be independently reported." 21 U.S.C. § 360b(l)(3)(E)(i). Congress further specified that "data shall be reported in a manner consistent with protecting both national security and confidential business information." 21 U.S.C. § 360b(l)(3)(E)(ii).

II. Plaintiff's FOIA Request

By letter dated February 10, 2011, Plaintiff submitted a FOIA request seeking "records related to sponsor submissions pursuant to Section 105 of [ADUFA]," specifically:

> (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.

Garcia-Malene Decl. (Ex. A) ¶ 5; see also Compl., Dkt. No. 1, ¶ 8; FOIA Request, Ex. A(1). FDA released records responsive to the first part of Plaintiff's request regarding educational and outreach materials. Plaintiff has not challenged FDA's response to the first part of its FOIA request. See Joint Status Reports, Dkt. Nos. 5, 6.

FDA denied Plaintiff's FOIA request regarding antimicrobial drug sales data, on the ground that they were exempt from disclosure. See Garcia-Malene Decl. (Ex. A) ¶ 7. After filing its Complaint, Plaintiff modified its FOIA request to seek data collected pursuant to Section 105 of ADUFA containing the *aggregated* amount of antimicrobial drugs sold for use in

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Garcia-Malene and other declarations will be cited in the parentheses following the citation to the declaration, such that Ex. 1 to the Garcia-Malene declaration, for example, is cited as Ex. A (1).

food producing animals in 2009, broken down by container size, strength, dosage form, and class of animal, for each antimicrobial class. See Joint Status Report, Dkt. No. 5.

FDA conducted a search for records responsive to this modified request and located two records that are partially responsive. FDA released these two partially responsive documents with redactions ("Document 1" and "Document 2") on April 8, 2013. Garcia-Malene Decl. (Ex. A) ¶¶ 9, 11 & Document 1 and Document 2, Exs. A(2) and A(3). Plaintiff does not challenge FDA's search or production of responsive records. See Joint Status Report, Dkt. No. 6, at 2. Nor does Plaintiff challenge FDA's redactions to Document 1. Garcia-Malene Decl. (Ex. A) ¶ 20. Plaintiff objects only to the redactions to Document 2, which contains sales data for 2009, for domestic and export sales, broken down by route of administration and antimicrobial class. Id. Pursuant to FOIA Exemptions 3 and 4, FDA redacted the following information from Document 2: all individualized sales data; all sales data comprised of aggregated data from two distinct sponsors; and sales data comprised of aggregated data from three or more distinct sponsors in those instances where, through simple arithmetic using information already released publicly by FDA, such data would reveal aggregated sales data from two distinct sponsors or individualized sales data. Id.[2]

Although the parties have worked diligently and amicably to narrow and/or resolve numerous issues in this case, they were unable to successfully resolve Plaintiff's objections to

[2] Plaintiff stated numerous times that Plaintiff seeks only *aggregated* data. See Compl., Dkt. No. 1, ¶ 21 (GAP now seeks "aggregated data concerning the amount of antimicrobial active ingredient sold for each class of antimicrobial drugs, *rather than data concerning sales and distribution by each individual sponsor*.") (emphasis added). See also Joint Status Report, Dkt. No. 5, ¶ 1; Garcia-Malene Decl. (Ex. A) ¶ 11. Forty-one numbers redacted from Document 2 represent the sales and distribution data for an individual sponsor, and thus, are not responsive to Plaintiff's FOIA request. Garcia-Malene Decl. (Ex. A) ¶ 11. Even if individual sales data were responsive to Plaintiff's request, these data are exempt from disclosure under the FOIA, as explained in further detail below. Therefore, only twenty-seven numbers are responsive but withheld pursuant to Exemptions 3 and 4.

the redactions to Document 2.

LEGAL STANDARD

Courts generally and appropriately resolve FOIA cases on motions for summary judgment. Customs & Int'l Trade Newsletter v. U.S. Customs & Border Prot., 588 F. Supp. 2d 51, 54 (D.D.C. 2008); Russell v. FBI, No. 03-0611, 2004 WL 5574164, at *2 (D.D.C. Jan. 9, 2004); see also Wheeler v. U.S. Dep't of Justice, 403 F. Supp. 2d 1, 5 (D.D.C. 2005) ("Summary judgment is the routine vehicle by which most FOIA actions are resolved."). Summary judgment should be granted when the "movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a),(c). A material fact is any fact that "might affect the outcome of the suit." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

In FOIA cases, "the defending agency must prove that each document that falls within the class requested either has been produced, is unidentifiable or is wholly exempt from the [FOIA's] inspection requirements." Weisberg v. U.S. Dep't of Justice, 627 F.2d 365 (D.C. Cir. 1980) (quoting Nat'l Cable Television Ass'n v. FCC, 479 F.2d 183, 186 (D.C. Cir. 1973)). A defendant may rely on affidavits or declarations to meet its burden. Hayden v. Nat'l Sec. Agency Cent. Sec. Serv., 608 F.2d 1381, 1384 (D.C. Cir. 1979); Russell, 2004 WL 5574164, at *2. As long as the declarations contain reasonably detailed and non-conclusory information, a court may grant summary judgment. See Wolf v. CIA, 473 F.3d 370, 374-75 (D.C. Cir. 2007) ("Ultimately, an agency's justification for invoking a FOIA exemption is sufficient if it appears 'logical' or 'plausible'"). See also Judicial Watch, Inc. v. U.S. Dep't of Def., 715 F.3d 937, 940-41 (D.C. Cir. 2013) ("[s]o long as [the declaration] 'describes the justifications for withholding the information with specific detail, demonstrates that the information withheld logically falls

within the claimed exemption, and is not contradicted by contrary evidence in the record or by evidence of the agency's bad faith, . . . summary judgment is warranted on the basis of the affidavit alone.'" (quoting ACLU v. U.S. Dep't of Def., 628 F.3d 612, 619 (D.C. Cir. 2011))).

In support of this motion, FDA submits the declarations from Gorka Garcia-Malene, CVM FOIA Officer and Neal Bataller, Director of the Division of Surveillance in CVM's Office of Surveillance and Compliance, attached at Ex. B (hereafter, "Bataller Decl."), as well as declarations submitted by representatives of most of the NADA sponsors who submitted the sales data at issue.[3] These declarations establish that FDA appropriately withheld the redacted sales data in Document 2 pursuant to FOIA Exemptions 3 and 4.

[3] Specifically, attached are the following declarations: Kelly W. Beers, Regulatory Manager at Huvepharma, Inc., attached at Ex. C ("Beers Decl."); Michael Mlodzik, Manager of Pharmaceutical Regulatory Affairs at Boehringer-Ingelheim Vetmedica, Inc., attached at Ex. D ("Mlodzik Decl."); Robert Zolynas, Vice President for Research and Development at Bayer HealthCare LLC, attached at Ex. E ("Zolynas Decl."); Deborah Chaleff, Regulatory Affairs Director at Intervet, Inc., doing business as Merck Animal Health, attached at Ex. F ("Chaleff Decl."); Warren M. Harper, Senior Vice President of Global Marketing at Phibro Animal Health Corporation, attached at Ex. G ("Harper Decl."); Jean L. Panier, Senior Finance Director for U.S. Operations of Zoetis, Inc., attached at Ex. H ("Panier Decl."); Richard Yates, Director of Commercial Compliance at ADM Alliance Nutrition, Inc., attached at Ex. I ("Yates Decl."); S. Lee Whaley, Director of Regulatory Affairs at Norbrook, Inc., attached at Ex. J ("Whaley Decl."); Gregory Bergt, Vice President, Regulatory Affairs at PennField Oil Company, doing business as Pennfield Animal Health, attached at Ex. K ("Bergt Decl."); Tracey Ward, Director of Regulatory Surveillance and Compliance for Elanco, a division of Eli Lilly and Company, attached at Ex. L ("Ward Decl."); Gary Bosch, Vice President of Sales and Marketing for Farm Animal Business at Novartis Animal Health US, Inc., attached at Ex. M ("Bosch Decl."); Gerald Macedo, President and Chief Executive Officer of Med-Pharmex, Inc., Ex. N ("Macedo Decl."); and Joseph J. Heath, Corporate Secretary and General Counsel for G.C. Hanford Manufacturing Co., Inc., attached at Ex. O ("Heath Decl.").

ARGUMENT

I. FDA APPROPRIATELY APPLIED FOIA EXEMPTIONS 3 AND 4[4]

FOIA requires executive branch agencies to make their records available "to any person" upon request, but contains nine exemptions from that disclosure requirement. 5 U.S.C. § 552(a)(3)(A), (b). Two of those exemptions, Exemption 3 and Exemption 4, apply to the sales data FDA redacted from Document 2. See 5 U.S.C. § 552(b)(3), (4). [5]

A. FDA Properly Redacted Information Under Exemption 3

FDA properly withheld the sales data in Document 2 pursuant to Exemption 3 of the FOIA because the statute that requires sponsors of NADAs containing antimicrobial active ingredients to submit sales data to the agency also limits disclosure of those data.

1. Section 105 of ADUFA Is a Withholding Statute

Exemption 3 provides that agencies may withhold information "specifically exempted from disclosure by statute." 5 U.S.C. § 552(b)(3); Pub. Citizen, Inc. v. Rubber Mfrs. Ass'n, 533 F.3d 810, 814 (D.C. Cir. 2008). To determine whether disclosure is specifically exempted by statute, courts look "at the language of the statute on its face." Zanoni v. U.S. Dep't of Agric., 605 F. Supp. 2d 230, 236 (D.D.C. 2009). To qualify as a withholding statute, the statute must

[4] As stated previously, Plaintiff does not challenge the scope or adequacy of FDA's search for records responsive to Plaintiff's request. See Joint Status Report, Dkt. No. 6, at 2. Therefore, FDA need not prove that its search was reasonably calculated to uncover responsive records as no issue of material fact exists regarding FDA's search. Kowalczyk v. U.S. Dep't of Justice, 73 F.3d 386, 388 (D.C. Cir. 1996) ("[I]f challenged," [an agency] "must demonstrate beyond material doubt that the search was reasonable." (quoting Truitt v. U.S. Dep't of State, 897 F.2d 540, 542 (D.C. Cir. 1990))).

[5] These exemptions apply with equal force to the individualized sales data redacted in Document 1. The redactions in Document 1 are not discussed separately in this memorandum because it is FDA's understanding that Plaintiff does not object to the redactions in Document 1. Moreover, as discussed supra in footnote 2, individualized sales data are not responsive to Plaintiff's request for aggregated data.

either "require[] that the matters be withheld from the public in such a manner as to leave no discretion on the issue," 5 U.S.C. § 552(b)(3)(A)(i), *or* "establish[] particular criteria for withholding or refer[] to particular types of matters to be withheld," 5 U.S.C. § 552(b)(3)(A)(ii).[6] A statute need only meet one of these conditions, Rubber Mfrs., 533 F.3d at 813.

Section 105 of ADUFA, codified at 21 U.S.C. § 360b(l)(3), qualifies as an Exemption 3 statute. Section 105 states that "[t]he Secretary shall make summaries of the information reported under this paragraph publicly available, except that–(i) the summary data shall be reported by antimicrobial class,[7] and *no class with fewer than 3 distinct sponsors* of approved applications *shall be independently reported*. " 21 U.S.C. § 360b(l)(3)(E)(i) (emphasis added). In addition to this plain prohibition, Congress further emphasized that the data in the summary reports "shall be reported in a manner consistent with protecting both national security and confidential business information." 21 U.S.C. § 360b(l)(3)(E)(ii). The statute's plain language thus requires that FDA, on behalf of the Secretary, withhold from the public the aggregated annual sales data for each antimicrobial class that has "fewer than 3 distinct sponsors" (i.e., aggregated sales data from only two distinct sponsors in an antimicrobial class and

[6] Section 552 of Title 5 also states that if the statute was "enacted after the date of enactment of the OPEN FOIA Act of 2009" the statute must "specifically cite[] to" 5 U.S.C. § 552(b)(3). The OPEN FOIA Act of 2009 was enacted on October 28, 2009. See Act of Oct. 28, 2009, 5 U.S.C. Pub. L. No. 111-83, 123 Stat. 2142. Section 105 of ADUFA was enacted on August 14, 2008, so this requirement does not apply. See Animal Drug User Fee Amendments of 2008, Pub. L. No. 110-316, 122 Stat. 3509.

[7] The antimicrobial classes are Aminocoumarins, Aminoglycosides, Amphenicols, Cephalosporins, Diaminopyrimidines, Fluoroquinolones, Glycolipids, Ionophores, Lincosamides, Macrolides, Penicillins, Pleuromutilins, Polypeptides, Quinoxalines, Streptogramins, Sulfas, and Tetracyclines. See 2009 Summary Report, Ex. A(4); Garcia-Malene Decl. (Ex. A) ¶ 19.

individualized sales data for any antimicrobial class with only one distinct sponsor).[8]

Section 105 of ADUFA is an Exemption 3 withholding statute under 5 U.S.C. § 552(b)(3)(A)(i) because it "requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue." Section 105 of ADUFA plainly states that classes "with fewer than 3 distinct sponsors" shall not be independently reported. 21 U.S.C. § 360b(l)(3)(E)(i).[9] Congress also emphasized that "the data shall be reported in a manner consistent with protecting . . . confidential business information." 21 U.S.C. § 360b(l)(3)(E)(ii). The statutory language is clear and leaves no room for discretion regarding the disclosure of annual sales data by antimicrobial class for antimicrobial classes with less than three distinct sponsors.[10]

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[8] FDA interprets a "distinct sponsor" for the purposes of determining how many distinct sponsors make up a particular antimicrobial class as a sponsor (1) that is "named in 21 C.F.R § 510.600 as the holder of an approved application for an animal drug product in that particular class on the last day of the annual reporting period" and (2) that "actively sold or distributed such animal drug product at some point during that annual reporting period." 2009 Summary Report, Ex. A(4); Bataller Decl. (Ex. B) ¶ 10.

[9] Importantly, the "independently reported" language in Section 105 of ADUFA prohibits more than just FDA's affirmative disclosure (in the Summary Report) of aggregated annual sales data by antimicrobial class for antimicrobial classes "with fewer than 3 distinct sponsors." It also prohibits FDA from releasing to the public *any* sales data broken down by antimicrobial class for antimicrobial classes "with fewer than 3 distinct sponsors."

[10]The plain language of the statute reveals Congress' appreciation for the dangers of disclosure and the sensitivity of the sales data. See Wis. Project on Nuclear Arms Control v. U.S. Dep't of Commerce, 317 F.3d 275, 281 (D.C. Cir. 2003) ("[T]he touchstone of the Exemption 3 inquiry is whether the statute 'is the product of congressional appreciation of the dangers inherent in airing particular data and incorporates a formula whereby the administrator may determine precisely whether disclosure in any instance would pose the hazard that Congress foresaw.'" (quoting Am. Jewish Cong. v. Kreps, 574 F.2d 624, 628-29 (D.C. Cir 1978))).

ADUFA's legislative history also reinforces that FDA's redactions were appropriate under Exemption 3. The House Report states that

> [t]he Secretary may share information reported under this section with the Antimicrobial Resistance Task Force . . . . As of the date of enactment of this Act,

Section 105 of ADUFA also satisfies the alternative condition in Exemption 3 because it "establishes particular criteria for withholding or refers to particular types of matters to be withheld." See 5 U.S.C. § 552(b)(3)(A)(ii). Section 105 of ADUFA articulates a clear rule for withholding particular types of information: "no class with fewer than 3 distinct sponsors of approved applications shall be independently reported." 21 U.S.C. § 360b(l)(3)(E)(i).

2. FDA Properly Applied Exemption 3 to the Sales Data in Document 2

The information redacted by FDA in Document 2 falls squarely within ADUFA Section 105's non-disclosure requirements. Specifically, FDA redacted the sales data for the antimicrobial classes with "fewer than 3 distinct sponsors" for a particular route of administration and for the antimicrobial class as a whole. In 2009, fewer than three distinct sponsors distributed or sold animal drugs domestically for the following antimicrobial classes: Aminocoumarins, Amphenicols, Diaminopyrimidines, Fluroquinolones, Glycolipids, Pleuromutilins, Polypeptides, Quinoxalines, and Streptogramins. See 2009 Summary Report, Ex. A(4); Garcia-Malene Decl. (Ex. A) ¶ 24. Additionally, fewer than three distinct sponsors exported animal drugs for the following antimicrobial classes: Aminocoumarins, Aminoglycosides, Amphenicols, Cephalosporins, Diaminopyrimidines, Fluoroquinolones, Glycolipids, Ionophores, Lincosamides, Macrolides, Penicillins, Pleuromutilins, Polypeptides, Quinoxalines, Streptogramins, and Sulfas. Id. Accordingly, FDA properly withheld sales data in

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> the Antimicrobial Resistance Task Force was composed solely of representatives from Federal agencies, as determined by the Secretary of Health and Human Services. It is the intention of this Committee that information reported under this section be available only to representatives of Federal agencies. If the membership of the Antimicrobial Resistance Task Force is ever expanded to include representatives of non-Federal agencies, the appropriate steps should be taken to ensure that representatives of non-Federal agencies only receive information consistent with what is provided publicly under this section.
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> H.R. Rep. 110-804, at 15, reprinted in 2008 U.S.C.C.A.N. at 1295.

Document 2 for these specific antimicrobial classes under Exemption 3.

In addition, pursuant to Exemption 3, FDA also properly redacted aggregated sales data from three or more distinct sponsors in eight instances: 1) Penicillins by "[i]njection" (domestic sales); 2) Penicillins for treatment of "[m]astitis" (domestic sales); 3) Penicillins by "[w]ater" (domestic sales); 4) Tetracyclines by "[i]njection" (domestic sales); 5) Tetracyclines by "[m]edicated [f]eed" (domestic sales); 6) Tetracyclines by "[w]ater" (domestic sales); 7) Sulfas by "[m]edicated [f]eed" (domestic sales); 8) Sulfas by "[w]ater" (domestic sales). Document 2, Ex. A(3). In these eight instances, as explained below, release of these data would have, in light of other publicly available information, revealed the aggregated sales data for two distinct sponsors or the data of individual sponsors. Garcia-Malene Decl. (Ex. A) ¶ 26.

To illustrate, FDA redacted all the domestic sales data for Sulfas, which were sold and distributed by four routes of administration in 2009: medicated feed, oral, oral/water, and water. Document 2, Ex. A(3). FDA properly redacted the sales data for the oral/water category, because there is only one distinct sponsor in that category (referred to in this example as Sponsor A). Similarly, FDA properly redacted the sales data for the oral category, because there are only two distinct sponsors in that category (referred to in this example as Sponsors A and B). Document 2, Ex. A(3). Although both the medicated feed and water categories have three or more distinct sponsors, if FDA released the Sulfas domestic sales and distribution totals for these two categories, Sponsor A, through simple arithmetic, could add these totals and then subtract them from the aggregated sales data for all Sulfas sold domestically, which was made public in the 2009 Summary Report (517, 873 kilograms). See Ex. A(4). Then, Sponsor A could subtract from this remaining number its own sales totals for oral and oral/water, and the remaining number would be Sponsor B's 2009 sales data for Sulfas administered orally. See Garcia-

Malene Decl. (Ex. A) ¶ 26. Because Section 105 prohibits FDA from independently reporting sales data for classes with "fewer than 3 distinct sponsors" and requires FDA to report the sales data in a manner that protects "confidential business information," 21 U.S.C. § 360b(l)(3)(E), FDA could not release the medicated feed and water aggregated data consistent with Congress' mandate.

Penicillins sold and distributed domestically provide another illustrative example. The sales data for Penicillins administered by medicated feed domestically is exempt from disclosure because, as discussed above, only two distinct sponsors marketed Penicillins administered by medicated feed in 2009. See Document 1 and Document 2, Exs. A(2), A(3). But FDA also redacted aggregated sales data for Penicillins sold and distributed domestically where there were three or more distinct sponsors who marketed the drug class for certain other routes of administration—by injection, for the treatment of mastitis, and administered by water. These redactions were made because, by using the total aggregated sales data for all domestic Penicillins that is publicly available in the 2009 Summary Report, competitors could reverse-calculate the aggregated sales data for the two distinct sponsors of Penicillins for medicated feed. This could be done by totaling the Penicillins sales data for injection, mastitis, and water and subtracting that total from the aggregated sales number in the 2009 Summary Report; the remainder would be the aggregated sales data for the two distinct sponsors of Penicillins for medicated feed.

Also, if FDA released the aggregated sales data for Penicillins administered other than in medicated feed, the two distinct sponsors who sold Penicillins administered by medicated feed could calculate their competitor's individualized sales data for medicated feed; this could be done by: (1) totaling the aggregated sales data for routes of administration other than medicated

feed and (2) adding the sponsor's own sales data for medicated feed, and (3) subtracting that total from the aggregated sales number in the 2009 Summary Report. See Garcia-Malene Decl. (Ex. A) ¶ 26. FDA used a similar analysis for the three redactions of Tetracylines by injection, medicated feed, and water.

Section 105 of ADUFA on its face explicitly prohibits the disclosure of this information and qualifies as an Exemption 3 statute.[11] For all of the foregoing reasons, FDA properly relied on Exemption 3 to withhold all of the redacted sales data in Document 2.

B. FDA Properly Redacted Information Under Exemption 4

FOIA Exemption 4 is intended to protect the interests of persons that submit information to government agencies from the competitive harm that would result from disclosure of that information.[12] Exemption 4 prohibits the disclosure of trade secrets[13] and confidential commercial or financial information. In this case, FDA redacted Document 2 pursuant to the second category of information in Exemption 4: information that is (1) commercial or financial, (2) obtained from a person, and (3) privileged or confidential. 5 U.S.C. § 552(b)(4).

1. The Redacted Information Is Commercial or Financial and Was Obtained From a Person

It is axiomatic that the redacted sales data are commercial and/or financial in nature and

[11] Sponsors recognize the confidential commercial nature of the sales data and believe that data is protected from disclosure based on the strong, unequivocal language in Section 105 of ADUFA that FDA is to shield their confidential commercial information from public exposure. See Mlodzik Decl. (Ex. D) ¶¶ 15, 17; Zolynas Decl. (Ex. E) ¶ 9; Chaleff Decl. (Ex. F) ¶¶ 11–12, 17; Harper Decl. (Ex. G) ¶ 8; Panier Decl. (Ex. H) ¶ 4; Yates Decl. (Ex. I) ¶ 17; Whaley Decl. (Ex. J) ¶ 4.

[12] FDA's regulations also protect this information, providing that "[d]ata and information submitted or divulged to [FDA] which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure." 21 C.F.R. § 20.61(c).

[13] FDA does not contend that the redacted information in Document 2 contains trade secrets.

were submitted by a "person." Records are commercial as long as the submitter has a "commercial interest" in them. Pub. Citizen Health Research Grp. v. FDA, 704 F.2d 1280, 1290 (D.C. Cir. 1983). Sales data is of commercial or financial interest to the sponsors who submitted it, and those data fall squarely within the meaning of "commercial" and "financial" under Exemption 4. See Landfair v. United States Dep't of Army, 645 F. Supp. 325, 327 (D.D.C. 1986) ("Examples of items generally regarded as commercial or financial information include: business sales statistics, research data, technical designs, overhead and operating costs, and information on financial condition."); see also Island Film, S.A. v. Dep't of Treasury, 869 F. Supp. 2d 123, 133 (D.D.C. 2012) (describing sales statistics as commercial information under Exemption 4).

The data at issue were also submitted by a "person." Under Exemption 4, a "'person' includes an individual, partnership, corporation, association, or public or private organization other than an agency." 5 U.S.C. § 551(2); Pub. Citizen Health Research Grp. v. Nat'l Insts. of Health (NIH), 209 F. Supp. 2d 37, 44 (D.D.C. 2002) ("There is no doubt that a corporation may be considered a 'person' for the purposes of exemption 4."). FDA received the sales and distribution data from corporations, who are "persons" within the meaning of Exemption 4.

2. The Redacted Information is Confidential

Finally, the information at issue is "confidential."[14] Different tests for confidentiality apply depending on how the commercial or financial information is obtained by the government. Where, as here, commercial or financial information is required to be submitted to an agency, courts assess whether that information is "confidential" under Exemption 4 using the substantial

[14] Sponsors keep the sales data confidential. See, e.g., Beers Decl. (Ex. C) ¶ 9; Mlodzik Decl. (Ex. D) ¶¶ 12–14; Zolynas Decl. (Ex. E) ¶ 9; Chaleff Decl. (Ex. F) ¶¶ 14–16; Harper Decl. (Ex. G) ¶¶ 12–14; Panier Decl. (Ex. H) ¶¶ 6–7; Yates Decl. (Ex. I) ¶¶ 12–14; Whaley Decl. (Ex. J) ¶ 6; Bergt Decl. (Ex. K) ¶ 11; Ward Decl. (Ex. L) ¶¶ 9–10; Macedo Decl. (Ex. N) ¶ 2.

competitive harm test articulated in Nat'l Parks & Conservation Ass'n v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974) ("Nat'l Parks I"), as modified by Nat'l Parks & Conservation Ass'n v. Kleppe, 547 F.2d 673, 679 (D.C. Cir. 1976).[15] Under that test, commercial or financial information is "confidential" within the meaning of Exemption 4 if the disclosure of the information is likely "(1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained." Nat'l Parks I, 498 F.2d at 770.

An agency need not prove "actual competitive harm." Pub. Citizen v. FDA, 704 F.2d at 1291. Instead, courts have interpreted the second prong to require a showing of "actual competition" and a "likelihood of substantial competitive injury." CNA Fin. Corp. v. Donovan, 830 F.2d 1132, 1152 (D.C. Cir. 1987). Moreover, "an agency opposing disclosure based on Exemption 4 is not required to provide a detailed economic analysis of the competitive environment." Int'l Trade Newsletter, 588 F. Supp. 2d at 56.

a. Animal drug sponsors' individual sales data is confidential commercial information

Many antimicrobial classes shown on Document 2 had only one distinct drug sponsor in 2009. See Exs. A(2), A(3). Additionally, many antimicrobial classes had only one distinct drug sponsor for a particular route of administration in 2009. Id. For example, as easily discerned from public information, such as Document 1, only one distinct sponsor marketed a Sulfa drug

[15] The FDCA compels companies to submit the sales data at issue in 21 U.S.C. § 360b(l)(3). See Garcia-Malene Decl. (Ex. A) ¶ 14; Mlodzik Decl. (Ex. D) ¶ 7; Zolynas Decl. (Ex. E) ¶ 4; Chaleff Decl. (Ex. F) ¶ 10; Yates Decl. (Ex. I) ¶ 7; Whaley Decl. (Ex. J) ¶ 4; Bergt Decl. (Ex. K) ¶¶ 6,8; Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin., 244 F.3d 144, 149 (D.C. Cir. 2001) (finding that submissions are mandatory where "actual legal authority" exists for the receipt of the information). Therefore, the National Parks test applies. See Critical Mass Energy Project v. Nuclear Regulatory Comm'n, 975 F.2d 871, 878 (D.C. Cir. 1992). When persons submit information voluntarily, which is not the case here, the Critical Mass test applies. See Critical Mass, 975 F.2d at 879 (holding that information is confidential if it is "customarily" not released by the submitter to the public).

for administration by oral/water in 2009. Id.

FDA redacted all of a drug sponsor's individualized sales data as confidential commercial information because disclosure of such data would likely cause substantial competitive harm. See Garcia-Malene Decl. (Ex. A) ¶ 34. The animal drug market is very competitive and highly price sensitive. See Garcia-Malene Decl. (Ex. A) ¶ 29; Beers Decl. (Ex. C) ¶ 8; Mlodzik Decl. (Ex. D) ¶ 18; Zolynas Decl. (Ex. E) ¶ 10; Chaleff Decl. (Ex. F) ¶ 18; Harper Decl. (Ex. G) ¶¶ 16,19; Yates Decl. (Ex. I) ¶18; Bergt Decl. (Ex. K) ¶ 9-10; Ward Decl. (Ex. L) ¶ 11; Heath Decl. (Ex. O) ¶ 14. See also Pub. Citizen v. NIH, 209 F. Supp. 2d at 47 ("The pharmaceutical industry is a highly competitive market where companies routinely attempt to discover a possible advantage over their competitors."). Therefore, any information relating to an antimicrobial drug sponsor's sales position would give its competitors a meaningful advantage.

Competition exists across routes of administration and across antimicrobial classes. Beers Decl. (Ex. C) ¶ 8; Mlodzik Decl. (Ex. D) ¶ 18; Harper Decl. (Ex. G) ¶¶ 16,19; Ward Decl. (Ex. L) ¶ 11, Macedo Decl. (Ex. N) ¶ 1.[16] Accordingly, the release of individualized sales data would allow many different competitors to more accurately estimate a company's production and/or manufacturing capacity. Beers Decl. (Ex. C) ¶ 10; Mlodzik Decl. (Ex. D) ¶ 19; Chaleff Decl. (Ex. F) ¶ 20; Yates Decl. (Ex. I) ¶ 19; Whaley Decl. (Ex. J) ¶ 7; Bergt Decl. (Ex. K) ¶ 10; Heath Decl. (Ex. O) ¶ 12. Competitors also could use the information to identify other companies' customers based on the types of antimicrobial drugs sold, estimate a company's production costs, change their pricing decisions to undercut another company's prices, and steal customers. Beers Decl. (Ex. C) ¶ 10; Mlodzik Decl. (Ex. D) ¶ 20; ; Zolynas Decl. (Ex. E) ¶¶ 8,

[16] Competition exists between generic and brand name companies. Zolynas Decl. (Ex. E) ¶ 10. Competition also exists between antimicrobial drugs sponsors and other non-antimicrobial drug sponsors "who market and sell their products as replacements" or alternatives to antimicrobial drugs. Harper Decl. (Ex. G) ¶ 23.

10; Chaleff Decl. (Ex. F) ¶ 21; Harper Decl. (Ex. G) ¶¶ 18–23; Yates Decl. (Ex. I) ¶ 19; Whaley Decl. (Ex. J) ¶ 7; Bergt Decl. (Ex. K) ¶ 10; Bosch Decl. (Ex. M) ¶ 4; Macedo Decl. (Ex. N) ¶ 3; Heath Decl. (Ex. O) ¶ 12. Courts have found that substantial competitive harm could result from the disclosure of information that would allow competitors to estimate and undercut bids. Gulf & W. Indus., Inc. v. United States, 615 F.2d 527, 530-31 (D.C. Cir. 1979). As one declarant explains, "[p]rice is one of the key elements of concern in the animal-health industry." Harper Decl. (Ex. G) ¶ 21.

Additionally, release of the sales data at issue would eliminate the need for competitors to do market research for certain products. Chaleff Decl. (Ex. F) ¶ 22. Drug sponsors pay substantial fees for market intelligence reports that roughly estimate sales data, and disclosure of a company's precise sales data in Document 2 would eliminate the need for these market reports and would most benefit competitors whose sales data are not included in Document 2. Id. Moreover, in this highly competitive market, many manufacturers with approved applications who are not currently distributing drug products can use information about sales volume to decide to actively market again. Mlodzik Decl. (Ex. D) ¶ 20. The release of the redacted sales data would reveal "if the market is ripe for a competing product." Beers Decl. (Ex. C) ¶ 10. Similarly, competitors can unfairly take advantage of significant investments by other sponsors by entering the most profitable sub-markets (revealed by the individualized sales data) and contracting with manufacturers for production on existing lines "that were built, licensed, and brought on-line with considerable investment from [another sponsor]." Mlodzik Decl. (Ex. D) ¶ 22; Chaleff Decl. (Ex. F) ¶ 24.

Release of the redacted sales data would also reveal the amount of active antimicrobial ingredient distributed by a sponsor, and could be used by competitors to purchase a significant

volume of that active antimicrobial ingredient to limit production by the sponsor. Mlodzik Decl. (Ex. D) ¶ 21; Chaleff Decl. (Ex. F) ¶ 23. Likewise, competitors who produce drugs with the same active ingredient and have a larger sales volume might try to "gain an advantage in negotiating their annual agreements with the active ingredient suppliers." Yates Decl. (Ex. I) ¶ 20. Furthermore, competitors could use the sales data to encourage customers to switch products by "implying 'over use'" of another sponsor's product. Zolynas Decl. (Ex. E) ¶ 8. All of these outcomes would amount to substantial competitive harm.

In Sharkey v. FDA, 250 Fed. Appx. 284, 290 (11th Cir. 2007), the Court recognized that "knowledge of [companies'] market share will allow a competitor to better estimate even more confidential information, such as production capacity and manufacturing specifics." Similarly, release of the redacted sales data here would allow competitors to better deduce other highly confidential information, such as manufacturing capacity and pricing strategies. Sharkey found that knowledge of a particular company's market share would likely cause competitive harm. Id. In this case, releasing individual companies' sales data would also reveal their market share and "strengths and weaknesses within the market." Bergt Decl. (Ex. K) ¶ 10; see also Beers Decl. (Ex. C) ¶ 10; Mlodzik Decl. (Ex. D) ¶19; Zolynas Decl. (Ex. E) ¶ 10; Panier Decl. (Ex. H) ¶ 8; Whaley Decl. (Ex. J) ¶ 7. Competitors could use the information to "shed light" on a company's "business emphasis," as well as which "product lines are receiving more focus" and "what product lines appear to be flagging and therefore more vulnerable." Chaleff Decl. (Ex. F) ¶ 20; see also Panier Decl. (Ex. H) ¶ 8. Thus, release of the redacted information would likely cause substantial competitive harm to the companies that submitted their confidential commercial information to FDA under Section 105 of ADUFA.

Courts have consistently protected individualized sales data under Exemption 4. See,

e.g., Pub. Citizen v. FDA, 704 F.2d at 1286 ("Congress clearly indicated that Exemption 4 *as a whole* could cover such materials as 'business sales statistics, inventories, customer lists, [and] scientific or manufacturing processes or developments'" (emphasis in original) (quoting H.R. Rep. No. 1497, reprinted in 1966 U.S.C.C.A.N. 2418, 2427)); Sharkey, 2007 WL 2914212, at *5 (holding that Exemption 4 exempts information about sales volume from disclosure); Heeney v. FDA, No. 99-56269, 2001 WL 371921, at *1 (9th Cir. Apr. 12, 2001) (finding that "marketing and sales data . . . falls squarely within the exemption provided by § 552(b)(4)"); Timken Co. v. U.S. Customs Serv., No. 79-1736, 1983 WL 486422, at *4 (D.D.C. June 24, 1983) (holding that sales data falls under Exemption 4 and that, even if the sales data was five to ten years old, substantial competitive harm could still result from its disclosure); Braintree Elec. Light Dep't v. U.S. Dep't of Energy, 494 F. Supp. 287, 289 (D.D.C. 1980) (holding that confidential commercial information includes information about a company's "selling prices, inventory balances, thruput charges, profit margins, purchase activity, freight charges, costs of goods sold"); cf. Jurewicz v. United States Dep't of Agric., 891 F. Supp. 2d 147, 154 (D.D.C. 2012) (finding that dog breeders' and dealers' sales volume was not confidential because the information "was already in the public domain").

Congress also recognized the confidential, commercial, and financial nature of these sales data. As explained in detail above, Section 105 of ADUFA requires FDA to withhold individualized sales data and aggregated sales data of less than three distinct sponsors and mandates that the agency report summary information in a manner that protects "confidential business information." 21 U.S.C. § 360b(l)(3)(E).

For all of these reasons, FDA properly redacted individual sales data in Document 2 as confidential commercial information exempt from disclosure under Exemption 4.

b. Aggregated sales data of two distinct sponsors is confidential commercial information

FDA also redacted from Document 2 aggregated sales data from only two distinct sponsors. Revealing the aggregated sales data of two distinct sponsors would allow a company's *most* direct competitor to easily subtract its sales data from the aggregate number to calculate its competitor's sales information. Garcia-Malene Decl. (Ex. A) ¶ 30; Mlodzik Decl. (Ex. D) ¶ 11. Additionally, for some antimicrobial classes where one company dominates the market, revealing the aggregated number would essentially reveal that individual company's sales data to knowledgeable competitors. Garcia-Malene Decl. (Ex. A) ¶ 30. FDA properly withheld as confidential commercial information the aggregated sales data for two distinct sponsors to protect revealing individualized sales data.

As detailed above, Congress also believed that aggregated sales data of two distinct sponsors needed to be protected and mandated that FDA withhold all sales data for antimicrobial classes "with fewer than 3 distinct sponsors." 21 U.S.C. § 360b(l)(3)(E). Thus, FDA properly redacted aggregated sales data of two distinct sponsors under Exemption 4.

c. Aggregated sales data of three of more distinct sponsors that would reveal aggregated sales data of two distinct sponsors or an individual sponsor's sales data if released is properly withheld as confidential commercial information

Courts have consistently taken into account the mosaic effect that occurs when information that, in and of itself would not cause substantial competitive harm if released, would likely cause substantial competitive harm if released in light of other publicly available information. See, e.g., Int'l Trade Newsletter, 588 F. Supp. 2d at 57 ("The information in question, when combined with publicly available . . . information, would provide companies with valuable knowledge regarding competitors' business operations."); Gilda Indus., Inc., v. U.S.

Custom & Border Prot. Bureau, 457 F. Supp. 2d 6, 13 (D.D.C. 2006) (holding that the government properly applied Exemption 4 as the disclosure of the information at issue "when cross-referenced with publically available . . . information . . . would reveal information that could cause substantial competitive harm").

In the eight instances described in supra Section I.A.2 (for three different antimicrobial classes, Penicillins, Tetracyclines, and Sulfas), and in four additional instances (for Injection, Mastitis, Medicated Feed, and Water for export), FDA also invoked Exemption 4 to redact aggregated sales data of three or more distinct sponsors that could be used along with publicly available information to reveal the aggregated sales data of two distinct sponsors or individualized sales data of a particular sponsor. See Garcia-Malene Decl. (Ex. A) ¶ 31. The analysis for FDA's redactions of the domestic aggregated sales data for Sulfas (for medicated feed and water), Penicillins (for injection, mastitis, and water) and Tetracyclines (for injections, medicated feed, and water), and of export aggregated sales data for certain routes of administration (Injection, Mastitis, Medicated Feed, and Water) is similar. See Garcia-Malene Decl. (Ex. A) ¶¶ 32–33. Moreover, Section 105 of ADUFA prohibits the release of aggregated sales data of fewer than three distinct sponsors by antimicrobial class. 21 U.S.C. § 360b(l)(3)(E)(i). As described above, the release of individualized sales data would likely cause competitive harm to the drug sponsors that submitted the information to FDA. Thus, FDA appropriately redacted this information under Exemption 4.

CONCLUSION

For the reasons discussed above, FDA properly redacted Document 2 under FOIA Exemptions 3 and 4. Plaintiff does not dispute the adequacy of FDA's search. No material issues of fact remain in dispute. For all of the foregoing reasons, FDA respectfully requests that

its motion for summary judgment be granted.

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Respectfully submitted,

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