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)

DEFENDANT'S REPLY IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFF'S CROSS-MOTION FOR SUMMARY JUDGMENT

The United States Food and Drug Administration ("FDA") respectfully submits this reply in support of its Motion for Summary Judgment and in opposition to Plaintiff's Cross-Motion for Summary Judgment.

INTRODUCTION

In its Motion for Summary Judgment, its accompanying Memorandum of Points and Authorities, and supporting declarations, FDA established that the agency properly redacted from two documents certain sales data submitted by sponsors of new animal drug applications ("NADAs") pursuant to Section 105 of the Animal Drug User Fee Amendments of 2008 ("ADUFA"), 110 P. L. 316, 122 Stat. 3509, codified at 21 U.S.C. § 360b(l)(3), because those data are exempt from disclosure under Exemptions 3 and 4 of the Freedom of Information Act ("FOIA"). In particular, FDA demonstrated that Section 105 of ADUFA is an Exemption 3

statute within the meaning of 5 U.S.C. § 552(b)(3), and that Section 105 prohibits the disclosure of all of the redacted information at issue. Additionally, FDA established that the redacted sales data are confidential commercial information that is exempt from disclosure under Exemption 4, 5 U.S.C. § 552(b)(4).

Plaintiff's Opposition and Cross-Motion confirms that the parties' dispute is a narrow one. Plaintiff does not challenge the scope or the adequacy of FDA's search. See Mem. in Opp'n. to Def.'s Mot. for Summ. J. and in Supp. of Pl.'s Mot. for Summ. J., Dkt. No. 9, ("Pl.'s Mem.") at 2. Additionally, Plaintiff agrees that the sales data at issue are both "commercial" and "obtained from a person." See id. at 19. Plaintiff also does not dispute that forty-one numbers redacted in Document 2 that represent the sales and distribution data for individual sponsors are not responsive to Plaintiff's FOIA request. See, e.g., Compl. ¶ 21; Joint Status Report, Dkt. No. 5, ¶ 1; Pl.'s Mem. passim. Additionally, Plaintiff is no longer challenging eight of FDA's redactions to Document 2. See Pl.'s Mem. at 42-43 ("Plaintiff has chosen not to contest Defendant's decision to withhold information in Document 2 concerning domestic sales of the following class/route combinations: Penicillins/Mastitis; Penicillins/Medicated Feed; Sulfas/Oral; Sulfas/Water; Sulfas/Oral/Water; Tetracyclines/Injection; Tetracyclines/Oral; Tetracyclines/Topical."). As a result, FDA was able to release the domestic sales data for Penicillins/Injection, Penicillins/Water, Sulfas/Medicated Feed, Tetracyclines/Medicated Feed, and Tetracyclines/Water. Therefore, only seventeen redactions remain in dispute. For the Court's convenience, those redactions are noted on Exhibit P.[1]

[1] For domestic sales, the following numbers are in dispute: Aminoglycosides/Injection, Cephalosporins/Injection, Fluoroquinolones/Injection, Cephalosporins/Mastitis, Aminoglycosides/Medicated Feed, Macrolines/Medicated Feed, Aminoglycosides/Oral, and Macrolides/Oral. For export sales, the following numbers are in dispute: Cephalosporins/Mastitis, Penicillins/Mastitis, and Tetracyclines/Medicated Feed.

In support of this Reply, FDA submits supplemental declarations from Neal Bataller, Director of the Division of Surveillance in the Center for Veterinary Medicine's ("CVM") Office of Surveillance and Compliance, attached as Ex. Q ("Bataller Supp. Decl."), and several of the NADA sponsors that submitted the sales data at issue in Document 2.[2]

ARGUMENT

As explained in Defendant's Motion for Summary Judgment, summary judgment is appropriate in a FOIA case when a government agency demonstrates that no material facts are in dispute and that each responsive record it has located has been produced to the plaintiff or is exempt from disclosure. Mem. of Points and Auth. in Supp. of Def.'s Mot. for Summ. J., Dkt. No. 8, ("Def.'s Mem.") at 5. Plaintiff's Opposition fails to rebut FDA's showing that Exemption 3 prohibits the disclosure of the seventeen sales figures that remain at issue or that the NADA sponsors that submitted those data are likely to suffer substantial competitive harm if the redacted sales data are released, rendering those data exempt from disclosure under FOIA Exemption 4. Defendant, therefore, has met its burden and is entitled to summary judgment.

Additionally, while Plaintiff's request sought data broken down by antimicrobial class, see Compl. ¶ 21, the following totals by route of administration (i.e., totals that combine classes by route of administration) are in dispute: Topical (domestic), Injection (export), Mastitis (export), Medicated Feed (export), Topical (export), and Water (export).

[2] Attached are the following declarations: Kelly W. Beers, Regulatory Manager for Huvepharma, Inc., attached at Exhibit R ("Beers Supp. Decl."); Jeet Uppal, Group Director of Global Market Research of Zoetis, Inc., attached at Exhibit S ("Uppal Decl."); Michael Mlodzik, Manager of Pharmaceutical Regulatory Affairs at Boehringer-Ingelheim Vetmedica, Inc., attached at Exhibit T ("Mlodzik Supp. Decl."); Warren M. Harper, Senior Vice President of Global Marketing at Phibro Animal Health Corporation, attached at Exhibit U ("Harper Supp. Decl."); Michael R. Daly, Denagard Brand Manager in Farm Animal Business, Novartis Animal Health US, Inc., attached at Exhibit V ("Daly Decl."); Tracy Ward, Director of Regulatory Surveillance and Compliance for Elanco, a division of Eli Lilly and Company, attached at Exhibit W ("Ward Supp. Decl."); and Gregory Bergt, Vice President, Regulatory Affairs at PennField Oil Company, doing business as Pennfield Animal Health, attached at Exhibit X ("Bergt Decl.").

I. FDA PROPERLY REDACTED THE SALES DATA IN DOCUMENT 2 PURSUANT TO FOIA EXEMPTION 3.

Pursuant to FOIA Exemption 3, an agency may withhold information "specifically exempted from disclosure by statute" either because the statute "requires 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* because it "establishes particular criteria for withholding or refers to particular types of matters to be withheld," 5 U.S.C. § 552(b)(3)(A)(ii).

As explained in FDA's Motion for Summary Judgment, Section 105 of ADUFA, codified at 21 U.S.C. § 360b(l)(3), qualifies as an Exemption 3 statute under both of these paragraphs. See Def.'s Mem. at 7-10. Section 105 requires 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). Section 105 further provides 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, 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). Section 105 also mandates that 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).[3] The statute's plain language thus reveals Congress' appreciation for the dangers of disclosure and the sensitivity of the sales data. See Wis. Project on Nuclear Arms Control v. United States Dep't of Commerce, 317 F.3d 275, 281 (D.C. Cir. 2003). Where "Congress has made plain its concern with a specific effect of publicity . . . Exemption 3 is to honor that concern." American Jewish Congress v. Kreps, 574 F.2d 624, 629 (D.C. Cir. 1978).

In opposition, Plaintiff argues that the limitations on disclosure in Section 105 apply only to the summary reports that FDA is instructed to make publicly available pursuant to that section, and not to disclosure under the FOIA. Plaintiff also argues that even if Section 105 is an Exemption 3 statute, FDA has applied it too broadly. As we show below, neither of these arguments has merit.

A. Section 105 Is An Exemption 3 Statute.

Section 105 prohibits FDA from making "publicly available" sales data for antimicrobial classes with "fewer than 3 distinct sponsors." See 21 U.S.C. § 360b(l)(3)(E)(i). Plaintiff incorrectly argues that Congress' placement of the language "the summary data shall be reported by antimicrobial class, and *no class with fewer than 3 distinct sponsors* of approved applications *shall be independently reported*" in the subsection (E) of Section 105 (21 U.S.C. § 360b(1)(E)) relates only to preparation and disclosure of summary reports, and therefore Congress intended that limitation to be inapplicable to any other disclosure, "such as in response to FOIA requests or to members of the Antibiotic Resistance Task force." Pl.'s Mem. at 12. But the presence of a disclosure requirement in Section 105 does not mean that the prohibitions on disclosure are

[3] Plaintiff incorrectly states that "Defendant has not claimed or argued that 21 U.S.C. § 360(1)(3)(E)(ii) is or would qualify as a FOIA Exemption 3 withholding statute." Pl.'s Mem. at 17 n. 2. FDA established that Section 105 of ADUFA, 21 U.S.C. § 360b(l)(3), which includes 21 U.S.C. § 360(1)(3)(E)(ii), is a withholding statute. See Def.'s Mem. at 7-10.

restricted to disclosures made in the summary reports. Indeed, other Exemption 3 statutes have included disclosure obligations.

In an analogous case, Doe v. Veneman, 380 F.3d 807 (5th Cir. 2004), the court held that the statute at issue, the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq, qualified as an Exemption 3 statute. Similar to Section 105, FIFRA "required certified applicators of restricted-use pesticides to maintain certain application records" and those records were available to federal and state agencies. 380 F.3d at 816. Compare 21 U.S.C. § 360b(l)(3)(A), (B), (D) (requiring sponsors of NADAs to maintain certain records on antimicrobial sales and distribution and making that information available to federal agencies). FIFRA also contained a disclosure requirement with a prohibition, similar to Section 105's. Pursuant to 7 U.S.C. § 136i-1(f), "The Secretary of Agriculture and the Administrator of the Environmental Protection Agency, shall survey the records maintained under subsection (a) of this section to develop and maintain a data base that is sufficient to enable the Secretary and the Administrator to publish annual comprehensive reports concerning agricultural and nonagricultural pesticide use." However, the statute provided further that "in no case may a government agency release data, including the location from which the data was derived, that would directly or indirectly reveal the identity of individual producers." 7 U.S.C. § 136i-1(b). Veneman held that the prohibition against disclosing information that would "directly or indirectly reveal the identity of individual producers" applied to public disclosures, including disclosures pursuant to the FOIA. 380 F.3d at 817. Similarly, Section 105's prohibitions, such as the prohibition against disclosing sales data for antimicrobial classes with "fewer than 3 distinct sponsors," apply to all public disclosures. In this same vein, Consumer Product Safety Commission v. GTE Sylvania, Inc., 447 U.S. 102, 107-08 (1980), rejected the argument that a

particular statute's nondisclosure requirements "appl[y] only when the Commission affirmatively undertakes to disclose information to the public, but not when it merely complies with a request for information under the FOIA." Plaintiff's argument likewise should be rejected as Section 105's withholding obligations apply to all public disclosures.

The legislative history confirms that FDA's reading of the statute's plain language is correct. Addressing how the sales data could be disclosed to members of the Antimicrobial Resistance Task Force, who were all representatives from government agencies, Congress explained:

> [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, 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.

Animal Drug User Fee Program-Revision and Extension, H.R. Rep. 110-804, at 15, reprinted in 2008 U.S.C.C.A.N. at 1295 (emphasis added). This legislative history demonstrates that Congress intended Section 105's disclosure limitations to affect what information is "publicly" available—not just what is included in the Summary Reports. This legislative history is also fatal to Plaintiff's contention that applying Section 105's disclosure limitations to the Task Force would leave that group unable to perform its function. See Pl.'s Mem. at 12-13. Congress clearly believed the Task Force would be capable of performing its functions using only the publicly available data if that group were to take on representatives from non-Federal agencies.

Apparently recognizing that the legislative history is incompatible with its cramped reading of Section 105's text, Plaintiff urges this Court to ignore it. See Pl.'s Mem. at 14-15

(arguing that "the legislative history of a statute may not be used to determine whether the statute qualifies as an Exemption 3 withholding statute."). In support, Plaintiff relies on the D.C. Circuit's decision in Reporters Committee v. DOJ, 816 F.2d 730, 735 (D.C. Cir. 1978), which emphasized that to find that a statute qualifies for Exemption 3, the court must find "a congressional purpose to exempt matters from disclosure in the actual words of the statute . . . not in the legislative history of the claimed withholding statute . . . ." See Pl.'s Mem. at 10-11. But Reporters Committee merely declined to use legislative history to find Congressional intent to prohibit disclosure where the statute itself did "not speak to the Attorney General's authority to disclose or refuse to disclose to the public." Id. at 735-36 ("[T]he government's argument is based not on the statutory language, but rather on the legislative history of the statute" and "legislative history will not avail if the language of the statute itself does not explicitly deal with public disclosure."). That is quite unlike the present situation, where the statute expressly prohibits disclosure of information and the legislative history simply confirms the meaning of the "congressional purpose" found in the statutory language. In any event, subsequent decisions in this Circuit and other circuits have analyzed relevant legislative history along with statutory language. See, e.g., Wis. Project, 317 F.3d at 282-85; Essential Information, Inc. v. United States Information Agency, 134 F.3d 1165, 1167 (D.C. Cir. 1998); A. Michael's Piano, Inc. v. FTC, 18 F.3d 138, 144 (2d Cir. 1994); Lesser v. U.S. Dep't of Commerce, 827 F.2d 1333, 1336 (9th Cir. 1987) (finding that "[t]he legislative history strongly suggests that Congress intended section 12(c)(1) to be an Exemption 3 statute").

Plaintiff also misses the mark in arguing that because Section 105's disclosure limitations do not specifically mention the FOIA, Congress did not intend for those limitations to apply to disclosures made under the FOIA. See Pl.'s Mem. at 13-14. As explained in FDA's Motion for

Summary Judgment, to qualify as an Exemption 3 statute, the statute need only explicitly cite to Exemption 3 of the FOIA if it was enacted after 2009. See 5 U.S.C. § 552(b)(3)(B). Section 105 of ADUFA was enacted in 2008. See Pub. L. No. 110-316, 122 Stat. 3509. Therefore, Congress did not need to cite to Exemption 3, and the absence of a reference to the FOIA in no way narrows the disclosure limitations evident in Section 105's plain language. Indeed, courts have repeatedly found statutes that do not reference the FOIA to qualify as Exemption 3 statutes. See, e.g., Newport Aeronautical Sales v. Dep't of the Air Force, 684 F.3d 160, 168 (D.C. Cir. 2012) (concluding that 10 U.S.C. § 130(a) is an Exemption 3 statute); Medina-Hincapie v. Dep't of State, 700 F.2d 737, 743-44 (D.C. Cir. 1983) (finding Section 222(f) of the Immigration and Nationality Act, 8 U.S.C. § 1202(f), to be an Exemption 3 statute).

For all of these reasons, this Court should reject Plaintiff's untenably narrow reading of Section 105's disclosure provisions. See Wis. Project, 317 F.3d at 284 (While the "FOIA undoubtedly demands a liberal presumption of disclosure . . . [an] unduly strict reading of Exemption 3 strangles Congress's intent and deprives the exemption of meaningful reach.").

B. Exemption 3 Applies To The Information Redacted in Document 2.

FDA established that Exemption 3 covers all of the redactions made in Document 2. Def.'s Mem. at 10-13. Plaintiff concedes that if the Court finds that Section 105 of ADUFA is an Exemption 3 statute, it should exempt from disclosure aggregated sales data for these classes: "Aminocoumarins, Amphenicols, Diaminopyrimidines, Fluroquinolones, Glycolipids, Pleuromutilins, Polypeptides, Quinoxalines, and Streptogramins." Pl.'s Mem. at 18. Nevertheless, Plaintiff continues to object to FDA's redaction of the figures noted on Ex. P.[4] For

[4] Plaintiff asserts that FDA's interpretation of Section 105 to apply to the specific redactions at issue in Document 2 is owed no deference. See Pl.'s Mem. at 16-17. But, once a court determines that a statute qualifies as an Exemption 3 statute, it may grant deference to the agency's interpretation of the statute. See Reporters Committee, 816 F.2d at 735 n.5 ("[I]t may

the reasons set forth in FDA's opening brief and below, FDA properly applied Exemption 3 to all of the data in dispute.

Section 105 of ADUFA states that "no class with fewer than 3 distinct sponsors of approved applications shall be independently reported." 21 U.S.C. § 360b(l)(3)(E)(i). Document 2 breaks down the sales data into domestic sales and export sales, and then further by route of administration, and then further by antimicrobial class. See Exhibit P. Pursuant to the withholding obligations set forth in Section 105, FDA first redacted all sales data for antimicrobial classes with fewer than three distinct sponsors in 2009. 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 Def.'s Mem. at 10, Def.'s Exs. A ¶ 24, A(4). Furthermore, 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. Therefore, for all of these routes of administration, FDA redacted the sales data. See Def.'s Mem. at 10.

Logically, this principle of "fewer than 3" also applies when antimicrobial classes broken down by a particular route of administration have fewer than three distinct sponsors. Congress' command not to release data from an entire class of drugs made up of fewer than three distinct sponsors necessarily required FDA to redact the data when broken down to the more granular

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be proper to give deference to an agency's interpretation of what matters are covered by a statute, once the court is satisfied that the statute is in fact an Exemption 3 withholding statute, i.e., that it meets both the threshold test and one prong of the proviso."); Church of Scientology Int'l v. DOJ, 30 F.3d 224, 235 (1st Cir. 1994) ("[U]nlike actions under other FOIA exemptions, agency decisions to withhold materials under Exemption 3 are entitled to some deference.")

level of route of administration because the dangers of releasing the data for antimicrobial classes with "fewer than 3 distinct sponsors" and releasing the data for antimicrobial classes with "fewer than 3 distinct sponsors" for a particular route of administration are exactly the same. See Wis. Project, 317 F.3d at 281 ("[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))). In both cases, when there are fewer than three distinct sponsors, the release of the redacted sales data would reveal confidential commercial information as there is actual competition both among the different classes of antimicrobial drugs and among different routes of administration. See Def.'s Mem. at 10-13, 16. Additionally, under this principle of "fewer than 3," FDA redacted aggregated sales data of three or more sponsors that, through simple arithmetic, would reveal the aggregated sales data for two distinct sponsors or individualized sales data. See Def.'s Mem. at 11-13.

FDA's application of the disclosure prohibition in Section 105 is further supported by Section 105's admonition that the data "shall be reported in a manner consistent with protecting . . . confidential business information." 21 U.S.C. § 360b(l)(3)(E)(ii). In order to protect confidential commercial information, FDA appropriately followed this instruction and redacted all individualized sales data, all aggregated sales data for two distinct sponsors, and all aggregated sales data for three or more sponsors that would reveal the aggregated sales data for two distinct sponsors or individualized sales data. Both 21 U.S.C. § 360b(l)(3)(E)(i) and (ii) required FDA to redact the aggregated sales data of fewer than three distinct sponsors and

aggregated sales data for three or more sponsors that would reveal aggregated sales data for two distinct sponsors or individualized sales data. Rather than being superfluous, 21 U.S.C. § 360b(l)(3)(E)(ii) establishes another criterion for withholding.[5]

II. FDA APPROPRIATELY REDACTED THE INFORMATION IN DOCUMENT 2 PURSUANT TO FOIA EXEMPTION 4.

Even if this Court determines that Section 105 of ADUFA is not an Exemption 3 statute, the information that was redacted from Document 2 is nevertheless exempt from disclosure under FOIA Exemption 4 because it is confidential commercial information. Exemption 4 protects, inter alia, information that is (1) commercial or financial, (2) obtained from a person, and (3) privileged or confidential. 5 U.S.C. § 552(b)(4). Plaintiff agrees that all of the information at issue is commercial and obtained from a person. Pl.'s Mem. at 19. Therefore, the only dispute is whether the information is confidential. Commercial information obtained from a person is confidential for purposes of Exemption 4 (when information is required to be submitted, as is the case here) if disclosure of the information would likely "cause substantial harm to the competitive position of the person from whom the information was obtained." Nat'l Parks & Conservation Ass'n v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974). In its opening brief,

[5] Indeed, the differences between 21 U.S.C. § 360b(l)(3)(E)(i) and (ii) are clear. For example, it is possible to aggregate the data received pursuant to Section 105 of ADUFA in different ways. In the 2009 Summary Report, the data is aggregated by antimicrobial class. See Def.'s Mem., Ex. A(4). In Document 2, the data is aggregated by antimicrobial class and also by route of administration. See id., Ex. P. FDA redacted both aggregations by antimicrobial class and aggregations by routes of administration. Id.

In particular, FDA redacted the aggregated sales total of the Topical route of administration for exports pursuant to 21 U.S.C. §360b(l)(3)(E)(ii) (as well as Exemption 4). Id. This redacted Topical total is an aggregated *route* total, not an *antimicrobial class* total, so 21 U.S.C. § 360b(l)(3)(E)(i), which discusses reporting *by antimicrobial class*, does not apply. Yet, FDA withheld the Topical total for export sales because the total is the aggregated sales data of only one distinct sponsor and therefore revealing that total would reveal confidential commercial information. See 21 U.S.C. § 360b(l)(3)(E)(ii). In this way, 21 U.S.C. §360b(l)(3)(E)(ii) provides another principle for FDA to apply to withhold information under Exemption 3.

FDA demonstrated that the sales data at issue is confidential, see Def.'s Mem. at 14-21; Def.'s Exs. A, C-O, by establishing that there is both actual competition and a likelihood of substantial competitive injury. See CNA Fin. Corp. v. Donovan, 830 F.2d 1132, 1152 (D.C. Cir. 1987) (to establish that the disclosure of information would cause substantial competitive harm for purposes of Exemption 4, an agency must show "actual competition" and a "likelihood of substantial competitive injury").

Plaintiff ignores the established case law cited by FDA which holds that Exemption 4 protects sales data from disclosure. Def.'s Mem. at 19.[6] Instead, Plaintiff argues that "other highly competitive industries," such as car manufacturers and the human pharmaceutical industry, "routinely" release information "concerning sales and production volume." See Pl.'s Mem. at 20. Even if that is true for some other industries, the argument has no bearing on the animal drug industry. The human pharmaceutical industry and animal drug industry differ.[7] Moreover, FDA's Motion for Summary Judgment established that in the animal drug industry,

[6] Rather than addressing the case law demonstrating that sales data are exempt from disclosure under Exemption 4, Plaintiff repeatedly explains the purpose of its FOIA request and its concerns about antimicrobial resistance. See, e.g., Pl.'s Mem. at 2-4, 21; Pl.'s Ex. 1 ¶¶ 9-16; Pl.'s Ex. 2. The purpose underlying Plaintiff's request has "no bearing on whether the information must be disclosed under FOIA." Bibles v. Oregon Natural Desert Ass'n, 519 U.S. 355, 356 (1997)(citing U.S. Dep't of Defense v. Fed. Labor Relations Auth., 510 U.S. 487 (1994)); see Consumers' Checkbook Center for the Study of Servs. v. U.S. Dep't of Health and Human Servs., 554 F.3d 1046, 1051 (D.C. Cir. 2009) ("The requesting party's intended use for the information is irrelevant to our analysis."); Public Citizen Health Research Group v. FDA, 185 F.3d 898, 904 (D.C. Cir. 1999) ("It is not open to [the requester], however, to bolster the case for disclosure by claiming an additional public benefit" as the "consequentialist approach to the public interest in disclosure is inconsistent with the '[b]alanc[e of] private and public interests' the Congress struck in Exemption 4.") (citations omitted); see also Dep't of Justice v. Reporters Comm. for Freedom of Press, 489 U.S. 749, 771 (1989) ("Except for cases in which the objection to disclosure is based on a claim of privilege and the person requesting disclosure is the party protected by the privilege, the identity of the requesting party has no bearing on the merits of his or her FOIA request.").

[7] For example, "[u]nlike the human pharmaceutical industry, animal health companies do not disclose their pipelines or research initiatives." Ward Decl. (Ex. V) ¶ 9.

sales data are not routinely released. See Def.'s Mem., at 14; Def.'s Exs. C-O. Plaintiff does not dispute that fact and instead offers only the unsupported assertion that "disclosure of such information can be quite beneficial" because it may help suppliers of raw materials better gauge future demand. See Pl.'s Mem. at 20.

As we show below, Plaintiff's contentions that FDA failed to establish actual competition within the antimicrobial animal drug market and that the sponsors that submitted the data at issue are not likely to suffer substantial competitive harm if the redacted sales data are released are unavailing.

A. Actual Competition Exists in the Antimicrobial Animal Drug Market.

FDA presented detailed declarations from NADA sponsors which establish that actual competition exists within the animal drug industry and that actual competition exists both among the different classes of antimicrobial drugs and among drugs with different routes of administration. See, e.g., Def.'s Mem., Ex. C ¶ 8; Ex. D ¶ 18; Ex. G ¶¶ 16, 19; Ex. L ¶ 11; Ex. N ¶ 1. As illustrated in Documents 1 and 2, there are multiple approved animal drugs within the same antimicrobial class and administered by the same route of administration, which shows that there is competition among these animal drug products. See Def.'s Mem., Exs. A(2), A(3), Ex P; Bataller Supp. Decl. (Ex. Q) ¶ 10. Even when there is only one animal drug product in a specific antimicrobial class for a particular route of administration, that animal drug product still faces competition. See Bataller Supp. Decl. (Ex. Q) ¶ 8. For example, "one sponsor has two approvals for the drug tiamulin (a Pleuromutilin) for the treatment of swine dysentery. One approval is for the use of tiamulin in medicated feed (NADA 139-472) and the other for its use in drinking water (NADA 140-916)." Id. Although "[t]here are no other approved *and* marketed tiamulin products available for this disease indication," id., "there are a number of other

marketed drugs in other antimicrobial classes (Aminoglycosides, Lincosamides, Macrolides, Polypeptides, Quinoxalines, Streptogramins, and Sulfas) that are approved for the treatment of swine dysentery. These products are available for administration through drinking water, medicated feed, and/or injection." Id.[8] There is competition between the different antimicrobial classes and different routes of administration because different active ingredients and routes of administration can be indicated for the same use. See Bataller Supp. Decl. (Ex. Q) ¶ 7.[9]

Plaintiff erroneously contends that FDA cannot show that "actual competition" exists unless the agency identifies the competing companies. See Pl.'s Mem. at 22. It is not necessary to specifically identify competitors by name to show actual competition. PETA v. USDA, No. 03-195, 2005 WL 1241141, at *5-6 (D.D.C. May 24, 2005). Nevertheless, some of the declarations submitted in support of FDA's Motion for Summary Judgment expressly named competitors. See Def.'s Ex. C ¶ 8; Ex. K ¶ 9. As a result, "Plaintiff does not contest Defendant's allegations concerning competition with respect to medicated feed drugs in all classes or mastitis products in the penicillins class." Pl.'s Mem. at 23. In any event, FDA established actual competition for all of the animal drugs at issue by referencing the number of

[8] Another example is mixed enteric infections: "Pleuromutilins treat mixed enteric infections. Other classes of antimicrobial drugs including [M]acrolides and [L]incosamides are also for the treatment of mixed enteric infections." Daly Decl. (Ex. U) ¶ 10.

[9] For example, the following animal drug products currently approved for the prevention, control, or treatment of bovine respiratory disease: 1) a Sulfa drug administered in drinking water, marketed by Boehringer Ingelheim Vetmedica, Inc; 2) a Macrolide drug administered by injection, also marketed by Boehringer Ingelheim Vetmedica, Inc; 3) a Sulfa drug administered by oral boluses, marketed by Cross Vetpharm Group, Ltd; 4) a Cephalosporin drug administered in drinking water, marketed by Zoetis, Inc.; 5) a Macrolide drug administered in drinking water, marketed by Elanco Animal Health; and 6) a Macrolide drug administered through medicated feed, also marketed by Elanco Animal Health. Id. ¶ 10. As this example illustrates, different antimicrobial drugs administered by different routes of administration compete with each other, because the market need for these animal drug products is finite and sponsors compete for similar customers. See Beers Supp. Decl. (Ex. R) ¶ 4 ("A primary reason for competition is because of a finite number of customers in the market place.")

competitors and/or the nature of the competition. See Def.'s Mem., Ex. A ¶ 29; Ex. B ¶ 8; Ex. D ¶ 18; Ex. E ¶10; Ex. F ¶ 18; Ex. G ¶¶ 16,19; Ex. I ¶ 18; Ex. J ¶ 6; Ex. L ¶ 11; Ex. N ¶ 1; Ex. O ¶¶ 3, 10, 14; Bataller Supp. Decl ¶¶ 7-13; PETA, 2005 WL at * 5-7 (finding that a declaration established actual competition because the declaration "list[ed] the number of competitors" and "describe[d] the nature of the competition" and the requester "ha[d] not offered evidence to contradict" the declaration). See also Mlodzik Supp. Decl. (Ex. T) ¶ 3 ("There are multiple potential substitutions available on the market that directly compete with each of BIVI's presentations and active ingredients. . . . For example, in the market for mastitis tubes for lactating cows, BIVI's products compete directly with four different products manufactured by Zoetis and Merck. . . . In the market for antibacterial products for use in cattle, BIVI markets three products, which compete directly with thirteen different products marketed by Merck, Zoetis, Elanco, Merial, Bayer, and Bimeda.").

FDA also presented evidence that competitors that hold approved NADAs, but that are not currently marketing all of their approved animal drugs, might decide to resume actively marketing their drugs based on the release of the redacted sales data.[10] See Def.'s Mem. at 17. In response, Plaintiff argues that "[e]vidence concerning the potential for future competitors to enter the industry is irrelevant." Pl.'s Mem. at 21-22. Yet, actual competition may be found based on future events. See General Elec. Co. v. Dep't of the Air Force, 648 F. Supp. 2d 95, 103

[10] Although Plaintiff states that FDA "has not presented any evidence demonstrating that any active participants in this market with approved but dormant applications actually exist," see Pl.'s Mem. at 35, FDA did provide evidence that some drugs that are the subject of approved NADAs are not currently marketed. For example, Document 1 provides a list of sponsors who reported to FDA that they marketed drugs in 2009. See Def.'s Mem., Ex. A(2). Additionally, FDA provided a link to information about currently approved NADAs. See id., Ex. B, ¶ 13. The information from these two sources can be used to determine which approved NADAs were not marketed in 2009. See also Bataller Supp. Decl. (Ex. Q) ¶ 13 ("[M]any competitors with approved NADAs exist that can decide to actively market again and thereby provide additional competition.")

(D.D.C. 2009) ("While there was technically no competition for these two contracts—since GE was awarded them on a sole source basis—GE has demonstrated that there remains actual competition over . . . future contracts with the Air Force."); cf Honeywell Technology Solutions, Inc. v. Dep't of the Air Force, 779 F. Supp. 2d 14, 23 (D.D.C. 2011) (A company "must put forward evidence of actual competition. But 'such evidence need not be of actual competition over th[is] particular contract.' Thus, [the company] need only present evidence that it faces competition regarding the types of services offered under the Contract.") (citations omitted).

For all of these reasons, FDA has shown that the sponsors of the redacted sales data face actual competition.

B. FDA Has Established that Disclosure of the Redacted Information in Document 2 is Likely to Cause Substantial Competitive Harm.

FDA's opening brief established that the release of the redacted sales data is likely to cause many different types of competitive harm and consequently the redacted sales data are exempt from disclosure under 21 U.S.C. § 552(b)(4). See Def.'s Mem. at 16-21; Def.'s Exs. C-O. Plaintiff's arguments to the contrary rely on unsupported assertions and speculation and should be rejected.

1. Release of the redacted sales data from 2009 is likely to cause substantial competitive injury.

Plaintiff argues at length that the sales data at issue are too old to cause competitive harm to the sponsors that submitted them if the data were disclosed. This argument fails for several reasons. First, contrary to Plaintiff's assertions, Pl.'s Mem. at 23-29, the animal drug market has not undergone "dramatic" changes since 2009. See Bataller Supp. Decl. (Ex. Q) ¶¶ 14-20. Although there were some increases and decreases in sales in the aggregate, many individualized animal drug products saw little change. Id. ¶ 15; Mlodzik Supp. Decl. (Ex. T) ¶ 6 ("For the

products for which Boehringer Ingelheim and Fort Dodge are listed as sponsors in Document 1, the amount of product distributed has not changed significantly since 2009. Thus the 2009 sales data are relevant and proportional to current trends in market share and production capacity and release continues to pose a competitive harm."); Daly Supp. Decl. (Ex. V) ¶ 8 ("Since Novartis was the only manufacturer of pleuromutilins in 2009 . . . the four year old data is still an excellent indicator of the size of the current tiamulin market.").

Moreover, sophisticated industry participants are aware of why changes occurred for some animal drug products, so industry participants could discern which products were likely to have seen sales increases or decreases. Bataller Supp. Decl. (Ex. Q) ¶ 16; see also Bergt Supp. Decl. (Ex. X) ¶ 8 ("[W]hile there have been changes in the relevant environment . . . for example pressures relating to demand, the events causing those changes are not secret, but are market variables which should be ascertainable by all in the industry. Thus, again in my opinion, anyone with knowledge of the industry could use the specifics for the year 2009 to make more accurate estimate[s] of quantities distributed in the current year and beyond than would be possible without the data."). For example, Plaintiff argues that droughts have led to an increased demand for antimicrobial drugs used to obtain greater feed efficiency. Pl.'s Mem. at 27. Not all of the drugs at issue in Document 2 are used to obtain greater feed efficiency. Bataller Supp. Decl. (Ex. Q) ¶ 16. Consequently, sophisticated competitors could estimate which product's sales remained constant, and which product's sales changed over the years. Thus, the release of the redacted sales numbers for the products that did not see much change is still likely to cause substantial competitive harm, for the reasons articulated in FDA's Motion for Summary Judgment and the accompanying exhibits. See Def.'s Mem. at 16-18; Def.'s Exs. C-O.

Second, many of the increases from 2009 to 2011 may be due to specific conditions at a particular moment, not long-lasting and transformative changes in the market. For example, "between 2009 and 2011, diseases such as clostridial dermatitis in turkeys and swine dysentery have resulted in sporadic and severe outbreaks in certain years and certain parts of the country. Drug sales fluctuations are often a factor of disease fluctuations and what drug products are preferentially used in outbreak situations and in certain parts of the country. Once the outbreak subsides, sales frequently return to previous levels." Bataller Supp. Decl. (Ex. Q) ¶ 18. Therefore, the 2009 sales data continue to have the ability to reveal current or future market conditions. See Bataller Supp. Decl. (Ex. Q) ¶ 15-20. Thus, the competitive harms described in FDA's opening brief are likely to occur. See Def.'s Mem. at 16-18, Def.'s Exs. C-O. Additionally, "[t]he individual sales data for each of these years then, even if variable, directly conveys important insights into each company's business performance under varying environmental and market conditions." Bataller Supp. Decl. (Ex. Q) ¶ 20.

Third, the release of the sales data reported in 2009 would reveal the precise sales data of individual drug sponsors, which makes these data very valuable to competitors, as current market intelligence reports only estimate the sales data for 2009. For example, there exists "some uncertainty about the accuracy of information coming from consultants and marketing companies in the industry. When developing predictions of future market activities (trend lines), the addition of true values (even 4 year old data) with current estimates would provide our competitors significantly more accuracy and confidence for planning their competitive activities." Beers Supp. Decl. (Ex. R) ¶ 6. See also Daly. Decl. (Ex. V) ¶ 10. Furthermore, the release of the redacted sales data would benefit some competitors more than others, as some competitors would not have data revealed because, for example, those competitors sales data are

excluded from Document 2 (because the competitors did not market in 2009), or are included in Document 2 only as an aggregation of three or more distinct sponsors. Such competitors would now have free, precise data about other sponsors' drugs. Thus, the release of the redacted sales data is likely to cause substantial competitive harm.

Finally, courts consistently have held that sales data are exempt from disclosure pursuant to Exemption 4, even when the sales data are five or more years old. See, e.g., Braintree Elec. Light Dep't v. U.S. Dep't of Energy, 494 F. Supp. 287, 290-91 (D.D.C. 1980) (finding that data from 1973 and 1974 "retain[ed] its importance in the 1980 market" and was confidential commercial information protected from disclosure by Exemption 4); Timken Co. v. U.S. Customs Serv., No. 79-1736, 1983 WL 486422, at *4 (D.D.C. June 24, 1983) ("Plaintiff, however, disputes that disclosure would cause any competitive harm because the contested information is allegedly stale. While it is true that the commercial information ranges from five to ten years old, there is no reason to believe that the [submitters of the information] would not be seriously injured by the disclosure of this information to plaintiff."). See also Zenith Radio Corp. v. Matsushita Elec. Corp., 529 F. Supp. 866, 891–92 (E.D. Pa. 1981) ("While at first blush one might doubt that harm could be caused by the disclosure of stale information, there is sense in the argument . . . that old business data may be extrapolated and interpreted to reveal a business' current strategy, strengths, and weaknesses. It would appear that, in the hands of an able and shrewd competitor, old data could indeed be used for competitive purposes.").

Plaintiff ignores these cases and instead relies on Lee v. F.D.I.C., 923 F. Supp. 451 (S.D.N.Y. 1996), for the claim that "competitive harm diminishes with the passage of time," see Pl.'s Mem. at 25. But Lee does not stand for such a broad proposition. Instead, Lee found that the government failed to adequately explain the "potential detriment" of releasing the

information at issue, especially as the information was otherwise publicly available in a different format. 923 F. Supp. at 455. Lee is very different from the situation here, where the redacted sales data are not publicly available and the declarations submitted in support of FDA's Motion for Summary Judgment establish that the disclosure of the redacted sales data from 2009 is likely to cause substantial competitive harm to the NADA sponsors. Plaintiff also relies on Center for Pub. Integrity v. Dep't of Energy, 191 F. Supp. 2d 187, 195 (D.D.C. 2002), but that case explicitly distinguishes the information at issue there (i.e., price data), from "more sensitive data," such as sales data.

For all the foregoing reasons, Plaintiff's contention that the release of the sales data from 2009 is not likely to cause substantial competitive harm in the current market is incorrect.

2. The competitive harms described by FDA are not likely to already occur based on publicly available information.

Plaintiff argues that even if the sales data from 2009 were relevant to the current animal drug industry, the disclosure of the redacted sales data would not increase the likelihood of competitive harm because information is already available to competitors that could be used to cause competitive harm. Pl.'s Mem. at 31. Yet, the release of the redacted sales data would be the missing key that would allow competitors to cause substantial competitive harm. See Daly Decl. (Ex. V) ¶ 6 ("Knowing sales volume provides the key missing piece for determining the value of the market").

Plaintiff contends that competitors would not be able to estimate a sponsor's current manufacturing capacity based on the release of the redacted sales data because the sales data are from 2009, and because, according to Plaintiff, it has not been established that knowing a sponsor's production capacity would allow a competitor to cause substantial competitive harm. As explained in supra Section II.B.1., the release of the sales data from 2009 is still likely to

cause substantial competitive harm. Furthermore, knowing a sponsor's production capacity and limitations would allow a competitor to "adjust either their price and or volume of production to maximize their return" as "[p]roduction capacity utilization is the key to keeping production costs low." Mlodzik Supp. Decl. (Ex. T) ¶ 5. This would "negatively impact [a sponsor] and would either force [the sponsor] to lower [its] price or decrease [its] production volume and drive up manufacturing cost[s]." Id. For this reason, the release of the redacted sales data is likely to cause substantial competitive harm. Specifically, "[k]nowing the production by kilogram of a product in a competitor's manufacturing plant allows a company to adjust production output. For example, if a plant is operated near capacity, a competitor can be assured that additional sales volumes will not be sought after. This allows the competitor to increase prices for additional units as demand increases." Id. As acknowledged by Plaintiff, a competitor's actions will depend on "whether the revenue generated by customer gains will sufficiently offset the foregone revenue from existing customers." Pl.'s Mem. at 33. The release of the redacted sales data would allow a competitor to better make this determination and cause substantial competitive harm.

Plaintiff further argues that likely customers can already be identified based on publicly available information. Yet, as explained in the declarations FDA submitted in support for its Motion for Summary Judgment, the release of the redacted sales data would allow a competitor to determine which products and customers it is worthwhile to *target*. See Def.'s Mem., Ex. H ¶ 8 ("Product sales and revenue information . . . would provide those competitors with insight into how much they should invest in specific areas in order to compete with Zoetis."); Id., Ex. J ¶ 7 (A competitor could use the information and if the competitor "deduced that Norbrook's market share of a given product was increasing (relative to the competitor's product), the

competitor could take aggressive marketing steps (e.g., decreasing price, offering volume purchase incentives, etc.) to capture market share from Norbrook."); Id., Ex. N ¶ 3 ("The release of the sales data to the public would allow competitors to . . . [d]ecide which products to replicate to compete with us [and] [a]ggressively target our customers in order to compete with us."); Id., Ex. O ¶ 13 ("Further, if a competitor or potential competitor were to learn the sales volume, it could help them evaluate the value of adding a competing product to their portfolio. Most generic penicillin manufacturers have limited production lines and space, and we are constantly making decisions about which products are best to manufacture."); Beers Supp. Decl. (Ex. R) ¶ 4 ("There are global (some in China) suppliers of most drugs (including bambermycins) who are looking for U.S. products to target.").[12] The release of the sales data would reveal market share and would provide greater insight into the animal drug products that are most profitable.

Plaintiff's contention that publicly available pricing information already enables competitors to undercut each other's prices is similarly flawed. See Pl.'s Mem. at 33. Publicly available pricing information is not sufficient to cause the harms that would likely be caused by the release of the redacted data. The release of the sales data would reveal a key part of the puzzle. See Beers Supp. Decl. (Ex. R) ¶ 5 ("The amount of potential revenue gain cannot be estimated based on price alone. The competitor would also need to know estimated sales and distribution to accurately estimate revenue. This is exactly the information that Huvepharma considers and maintains as confidential and that is redacted in Document 2."). For this reason,

[12] For the same reason, Plaintiff's contention that "[a] competitor seeking to limit another sponsor's production or increase its production costs by choking the supply of a needed active ingredient already has all the information necessary to do so" (Pl.'s Mem. at 36) is not correct.

the release of the redacted sales data would make it more likely that a competitor would cause substantial competitive harm by undercutting another sponsor's prices.[13]

Finally, as discussed in FDA's opening brief and above, the release of the precise sales data reported in 2009 would provide more accurate data than provided by the rough estimates currently available. Bergt Supp. Decl. (Ex. X), ¶ 7 ("I am unaware of, currently, any publication of accurate data regarding the quantity of Type A Medicated Articles distributed by manufacturer for any year."). Furthermore, a competitor's "ability to forecast the product sales of its competitors . . . places it at a significant competitive advantage." Uppal Decl. (Ex. S) ¶ 8. Consequently, many sponsors "use predictive analytics when engaging in forecasting." Id. If the redacted sales data were released, "market intelligence providers (or competitors who develop their own predictive models) could use the actual sales information from 2009 to validate existing predictive models, or to develop new ones. Those validated, more accurate models could then be used to generate more accurate forecasts of competitor market share and product sales." Id., ¶ 10. Again, because not all competitors' sales data are included in

[13] Plaintiff's attempts to distinguish two cases, Gulf & W. Indus., Inc. v. United States, 615 F.2d 527 (D.C. Cir. 1979), and Abou-Hussein v. Mabus, 2010 U.S. Dist. LEXIS 115032 (D.S.C. 2010) are unavailing. See Pl.'s Mem. at 34. In both these cases, the courts found a risk of competitive harm based on the ability of competitors to estimate or undercut bids. Plaintiff argues that these cases are inapposite because there is no evidence of an analogous procurement process for the animal drug industry. Pl's. Mem. at 34. But, in the animal drug industry, there is in fact a procurement process and in that process, the prices offered for animal drugs are not public. See Harper Supp. Decl. (Ex. U), ¶ 5 ("Some customers put out a formal Request for Bid or Request for Pricing (RFP) to the industry for products. . . . Requests from a procurement group or RFPs are used in the animal health industry and the content of such bids (including pricing) is confidential.") FDA has established that the release of the redacted sales data would allow competitors to undercut prices. See Def.'s Mem. at 16-17. Plaintiff also concedes that in the "procurement context, where procurement is carried out by soliciting bids from different companies, and where the prices and other content of companies' bids is kept secret from competitors, knowledge of competitor's pricing capabilities may indeed be quite advantageous." Pl.'s Mem. at 34. Therefore, the release of the redacted sales data would increase a competitor's ability to estimate and undercut bids and that is likely to cause substantial competitive harm.

Document 2, and because some sponsors' sales data in Document 2 is only in aggregations with more than three distinct sponsors, this would give some competitors an unfair advantage. See Def.'s Mem., Ex. L ¶ 16.

Again, individualized sales data are not responsive to Plaintiff's request. See Def.'s Mem. at 4 n.2; Compl. ¶ 21; Joint Status Report, Dkt. No. 5, ¶ 1; Pl.'s Mem. passim. To the extent that Plaintiff's arguments apply to the redactions at issue, for all of the reasons discussed in FDA's opening brief and accompanying declarations, the release of the redacted sales data are likely to cause substantial competitive harm.[14]

CONCLUSION

FDA has met its burden and established that the redacted sales data in Document 2 is protected from disclosure pursuant to Exemptions 3 and 4.[15] Accordingly, FDA respectfully requests that this Court grant FDA's Motion for Summary Judgment and deny Plaintiff's Cross-Motion for Summary Judgment.

Dated: September 13, 2013

[14] Additionally, courts "generally defer to the agency's predictive judgments as to 'the repercussions of disclosure.'" United Techs. Corp. v. U.S. Dep't of Def., 601 F.3d 557, 563 (D.C. Cir. 2010) (citations omitted).

[15] Even if a record contains some information exempt from disclosure, an agency must disclose any "reasonably segregable" information under the FOIA. See 5 U.S.C. § 552(b). Here, FDA disclosed all reasonably segregable information, as seen by Documents 1 and 2. See Def.'s Mem., Exs. A(2) and A(3). Furthermore, the Declaration of Gorka Garcia-Malene explained how FDA performed a thorough analysis to determine which numbers needed to be redacted. See Def.'s Mem., Ex. A, ¶ 12, 21, 24-26, 28, 30-33.

Moreover, FDA did not withhold any documents in their entirety, and only made redactions in Document 2 to information exempt from disclosure under Exemptions 3 and 4 of the FOIA. Id. Additionally, most of the redactions made were to individualized sales data, which is not responsive to Plaintiff's request. See Def.'s Mem. at 4 n.2; Compl. ¶ 21; Joint Status Report, Dkt. No. 5, ¶ 1; Pl.'s Mem. passim. Thus, FDA has satisfied all of its obligations with respect to Plaintiff's FOIA request.

Respectfully submitted,

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