VIROPHARMA INCORPORATED v. DEPARTMENT OF HEALTH AND HUMAN SERVICES et al Doc. 43

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

VIROPHARMA INCORPORATED, Plaintiff, v. DEPARTMENT OF HEALTH AND HUMAN SERVICES, and FOOD AND DRUG ADMINISTRATION, Defendants.	Civil Action No. 08-2189 (PLF)

OPINION

This matter is before the Court on cross-motions for summary judgment filed by the plaintiff, ViroPharma Incorporated, and the defendants, the Department of Health and Human Services ("HHS") and the Food and Drug Administration ("FDA"), and on ViroPharma's motion for *in camera* review. Upon consideration of the parties' papers, the relevant statutes and case law, and the entire record in this case, the Court will grant in part and deny in part defendants' motion, and will deny plaintiff's motions for summary judgment and for *in camera* review.[1]

[1] The papers reviewed in connection with the pending motions include: plaintiff's complaint ("Compl.") [Dkt. No. 1]; defendants' motion for summary judgment ("Def. Mot.") [Dkt. No. 28]; plaintiff's cross-motion for summary judgment and/or *in camera* review and opposition to defendants' motion ("Pl. Mot.") [Dkt. Nos. 30, 32]; defendants' reply to plaintiff's opposition and opposition to plaintiff's motion ("Def. Reply") [Dkt. No. 34]; and plaintiff's reply to defendants' opposition ("Pl. Reply") [Dkt. No. 37].

Dockets.Justia.com

I. BACKGROUND

ViroPharma owns the new drug application ("NDA") for Vancocin, a vancomycin hydrochloride capsule ("vancomycin"). Declaration of Thomas F. Doyle ("Doyle Decl.") ¶ 2, May 27, 2010 [Dkt. No. 30-2]. Vancocin is indicated for the treatment of a dangerous gastrointestinal infection caused by *Clostirdium difficile* bacteria. Compl. ¶ 2. At present, there is no FDA-approved generic version of vancomycin, and Vancocin is the only FDA-approved drug to treat *C. difficile* infections. Id.

Prior to 2006 the FDA recommended using *in vivo* studies — which involve testing in humans — to establish the bioequivalence of generic versions of vancomycin. Doyle Decl. ¶¶ 3-4. ViroPharma contends that, in February 2006, FDA adopted a new policy, recommending *in vitro* studies — which do not require testing in humans — as sufficient to establish bioequivalence. Doyle Decl. ¶ 4. Allegedly, FDA did not publicly announce the change in policy, but provided information to companies that submitted inquiries regarding the bioequivalence standards for vancomycin. Id. ¶ 5. ViroPharma learned of these events through one such company, which publicly released the new standards, leading to a reduction in the value of ViroPharma's stock by roughly 40%. Id. ¶¶ 6-7.

On March 17, 2006, ViroPharma filed a citizen petition for a stay of any approvals of abbreviated new drug applications ("ANDA") under FDA's new bioequivalence testing method. Doyle Decl. ¶ 8. On March 21, 2006, ViroPharma also filed a Freedom of Information Act request. Doyle Decl. ¶ 9. ViroPharma requested:

> A copy of the entire administrative record of the decision of the Office of Generic Drugs (OGD) (including, but not limited to, documents related to reference number: OGD #06-0200) that

> abbreviated new drug applications (ANDAs) or applications filed under 505(b)(2) for vancomycin hydrochloride capsules qualify for a waiver of *in vivo* bioequivalence and may demonstrate bioequivalence to the reference listed drug Vancocin® through *in vitro* dissolution testing.

Compl. ¶ 29. FDA logged the request into its tracking system and forwarded the request to the Division of Information and Disclosure Policy ("DIDP") in FDA's Center for Drug Evaluation and Research. Declaration of Frederick J. Sadler ("Sadler Decl.") ¶¶ 6-7, April 22, 2010 [Dkt. No. 28-2].

On December 16, 2008, FDA published a notice in the Federal Register entitled "Draft Guidance for Industry on Bioequivalence Recommendation for Vancomycin HCI; Availability." Doyle Decl. Ex. 3. Although the notice did not contain the administrative record for FDA's March 2006 decision, it did limit the use of *in vitro* testing to generic vancomycin tablets whose inactive ingredients are qualitatively and quantitatively the same as Vancocin; for others, *in vivo* testing was recommended. Doyle Decl. ¶¶ 12-13.

On December 16, 2008, ViroPharma filed this lawsuit to enforce FDA's obligations under the FOIA and submitted a second FOIA request seeking records related to the 2008 Draft Guidance. Doyle Decl. ¶¶ 14-15. ViroPharma's second request sought

> [a] copy of all records of the decision of the Food and Drug Administration (including, but not limited to, documents related [to] FDA's Draft Guidance for Industry on Bioequivalence Recommendation for Vancomycin HCL assigned docket number FDA-2008-D-0626) recommending in vitro dissolution studies for test formulations of Vancomycin HCL that are qualitatively (Q1) and quantitatively (Q2) the same as the reference listed drug with respect to inactive ingredients and recommending in vivo bioequivalence studies with clinical endpoints for test formulations that are not Q1 and Q2 the same as the RLD with respect to inactive ingredients; including . . . [a]ny Agency communication(s)

> regarding the above recommendations with any third party outsidde of the FDA prior to December 15, 2008.

Sadler Decl. Ex. B. FDA routed both of ViroPharma's requests to DIDP and the Office of the Executive Secretariat; Office of Legislation; Office of Policy, Planning, and Preparedness; and Office of the Chief Counsel. Sadler Decl. ¶¶ 8, 11.

On March 22, 2009, FDA produced documents in response to ViroPharma's FOIA requests from the Office of the Commissioner of the FDA. Doyle Decl. ¶ 16. On October 28, 2009, FDA produced additional documents from the Center for Drug Evaluation and Research. Id. Between November 11, 2009 and March 24, 2010, ViroPharma sent letters identifying documents it believed were responsive but had not been released. Id. ¶ 17. FDA released additional documents on December 9, 2009; February 24, 2010; and April 22, 2010. Id. ¶¶ 21, 25, 27. Throughout FDA's releases, it has withheld, in whole or in part, over 700 documents pursuant to the deliberative process privilege under FOIA Exemption 5. Sadler Decl. ¶¶ 23-24.[2] It has withheld over 100 documents pursuant to Exemption 4. Sadler Decl. ¶ 28. And it has withheld a "handful of records[]" pursuant to Exemption 6. Sadler Decl ¶ 35.

On April 22, 2010, defendants filed a motion for summary judgment in this case. With their motion, they included a *Vaughn* index listing the documents withheld; the documents' length; whether the documents were withheld in whole or in part; and the justifications for the withholdings. Sadler Decl. Ex. C. ViroPharma filed a cross-motion for summary judgment on May 27, 2010. ViroPharma requested that the Court require FDA to provide it with a number of

---

[2] It also withheld documents under Exemption 5 on the basis of attorney-client privilege and attorney work-product privilege. But those matters are no longer at issue in this case. See infra at 12 n.6.

documents and portions of documents FDA is withholding under Exemptions 4 and 5, and to conduct an *in camera* review of the withheld documents. Pl. Mot. at 12, 24, 30. In concert with defendant's reply brief, FDA has released to ViroPharma several documents it had been withholding under Exemptions 4 and 5. See, e.g., Second Declaration of Frederick J. Sadler ("Sadler Decl. Reply") ¶ 9, June 30, 2010 [Dkt. No. 34-2]; Second Declaration of Nancy B. Sager ("Sager Decl. Reply") ¶¶ 6, 11, 21, June 24, 2010 [Dkt. No. 34-3].

II. LEGAL STANDARD

Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment is appropriate if the movant shows that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law. FED. R. CIV. P. 56(a). The movant bears the burden of demonstrating the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). Factual assertions in the moving party's affidavits or declarations may be accepted as true unless the opposing party submits its own affidavits or declarations or documentary evidence to the contrary. Neal v. Kelly, 963 F.2d 453, 456 (D.C. Cir. 1992).

The FOIA requires a federal agency to release all records responsive to a proper request except those protected from disclosure by one or more of nine enumerated exemptions set forth in 5 U.S.C. § 552(b). See 5 U.S.C. § 552(b). FOIA cases typically and appropriately are decided on motions for summary judgment. See Defenders of Wildlife v. U.S. Border Patrol, 623 F. Supp. 2d 83, 87 (D.D.C. 2009); Bigwood v. U.S. Agency for Int'l Dev., 484 F. Supp. 2d 68, 73 (D.D.C. 2007). The agency opposing the grant of summary judgment has the burden of

proving that "each document that falls within the class requested either has been produced, is unidentifiable, or is wholly exempt from the Act's inspection requirements." Goland v. CIA, 607 F.2d 339, 352 (D.C. Cir. 1978) (internal citation and quotation omitted); see Maydak v. Department of Justice, 218 F.3d 760, 763-64 (D.C. Cir. 2000). The court may award summary judgment to an agency solely on the basis of information provided in affidavits or declarations that describe "the documents and the justifications for nondisclosure with reasonably specific detail, demonstrate that the information withheld logically falls within the claimed exemption, and are not controverted by either contrary evidence in the record nor by evidence of agency bad faith." Military Audit Project v. Casey, 656 F.2d 724, 738 (D.C. Cir. 1981); see Hertzberg v. Veneman, 273 F. Supp. 2d 67, 74 (D.D.C. 2003). A *Vaughn* index is a common device used by agencies to meet this burden of proof. See Judicial Watch v. FDA, 449 F.3d 141, 146 (D.C. Cir. 2006); Vaughn v. Rosen, 484 F.2d 820, 826 (D.C. Cir. 1973).

III. DISCUSSION

Defendants state that FDA's search was reasonably calculated to uncover all responsive records. Def. Mot. at 10. They provide declarations from FDA's Director of the Division of Freedom of Information and FDA's Director of Information Disclosure Policy describing the search conducted in response to ViroPharma's requests. See Sadler Decl; Declaration of Nancy B. Sager ("Sager Decl."), April 22, 2010 [Dkt. No. 28-3]. ViroPharma does not contend that FDA's search was insufficient. Instead, ViroPharma argues that FDA improperly withheld relevant documents under Exemptions 4 and 5. Pl. Mot. at 2, 12, 24. In addition, ViroPharma argues that FDA did not properly segregate factual material that it is

entitled to receive under the FOIA. Id. at 11. And finally, ViroPharma argues that *in camera* review is necessary in this case, primarily because, they assert, FDA has acted in bad faith. Pl. Reply at 21.[3]

A. Exemption 4

FOIA Exemption 4 protects from disclosure matters that are "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). Typically, materials implicating Exemption 4 are not generated by the agency, but are obtained from third parties either by request or by statutory or regulatory requirements. Judicial Watch, Inc. v. FDA, 449 F.3d at 148. Such commercial or financial information received from third parties is deemed confidential if disclosure of the information is likely (1) to impair the government agency's ability to obtain necessary information from third parties in the future, or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained. Id.; Nat'l Parks and Conservation Ass'n v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974). ViroPharma disputes FDA's withholding under Exemption 4 with respect to two categories: information referencing pending ANDAs, and incoming correspondence from drug manufacturers.

---

[3] FDA has redacted portions of several documents under FOIA Exemption 6 because the sections contain personal identity information. See 5 U.S.C. § 552(b)(6); Sadler Decl. ¶ 35, April 22, 2010 [Dkt. No. 38-2]. Exemption 6 "allows an agency to withhold 'personnel and medical files and similar files the disclosure of which would clearly constitute an unwarranted invasion of personal privacy.'" Reliant Energy Power Generation, Inc. v. FERC, 520 F. Supp. 2d 194, 207 (D.D.C. 2007). ViroPharma does not dispute the validity of these withholdings, and the FDA has demonstrated that the redactions are appropriate under Exemption 6. Consequently, the Court will grant defendants' motion for summary judgment with respect to these redactions.

1. Documents Referencing Pending ANDAs

Defendants argue that all information referencing pending ANDAs may properly be withheld under Exemption 4 because FDA is barred by its own regulations from releasing any information about a drug application prior to its approval, see 21 C.F.R. §§ 314.430(d), 314.430(e); because "information about the existence, identity, and status for new drug applications . . . constitutes 'commercial' information in that it reflects a company's business plans and marketing strategies"; and because "a company's plans about prospective products are closely guarded commercial secrets." Def. Mot. at 23-25.[4]

ViroPharma accepts the proposition that "the identity of the ANDA filers, information contained in the ANDAs, information regarding the approval status of the ANDAs, trade secret information such as drug formulas or manufacturing processes, or confidential commercial information" all are properly exempt under Exemption 4. Pl. Reply at 9. ViroPharma argues that with respect to approximately 70 documents, however, FDA over-claims Exemption 4 by removing all information that references pending ANDAs. Id. ViroPharma appears to request that FDA release the portions of documents that "reference" pending ANDAs, but are not covered within the above list. The Court, however, cannot discern any portion of the documents that would "reference" pending ANDAs but does not discuss information contained in the ANDAs or implicate the approval process. ViroPharma itself provides no indication of what such information might be.

[4] FDA also claims that the information referencing pending ANDAs is nonresponsive because pending ANDA filings are not considered when developing FDA's bioequivalence recommendations for vancomycin. See Def. Mot. at 23. Because the Court concludes that FDA has properly withheld this information under Exemption 4, it need not reach this argument.

The content of pending drug applications may be withheld under Exemption 4 where it contains safety and effectiveness information obtained through preliminary trials, evidence of side effects and their magnitude, or "drug product manufacturing information or drug chemical composition and specifications." Appleton v. FDA, 451 F. Supp. 2d 129, 141 n.7 (D.D.C. 2006). Although "[c]onclusory and generalized allegations of substantial competitive harm . . . cannot support an agency's decision to withhold requested documents[]" in the context of pending drug applications, Public Citizen Health Research Group v. FDA, 185 F.3d 898, 906 (D.C. Cir. 1999) (quoting Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1291 (D.C. Cir. 1983)), ViroPharma acknowledges that the content of pending ANDAs for vancomycin is protected by Exemption 4. See Pl. Reply at 9; see also Judicial Watch v. FDA, 449 F.3d at 148-49. Information that discusses or analyzes this protected content is similarly properly withheld.[5]

ViroPharma lists specific documents in which whole paragraphs have been redacted and argues that only the names of filers and the drug formula should have been redacted and the rest of the paragraph released. Pl. Reply at 9-14. If it were the case that this was the only information that could properly be redacted under Exemption 4, then the FDA would be required to redact the name and formula and provide the rest. As noted, however, ViroPharma acknowledges that Exemption 4 covers more than just the names of filers and drug formulas. The Court concludes that FDA has properly redacted portions of these documents under the

[5] To the extent that ViroPharma's distinction between its list of properly withheld material and documents "referencing" pending ANDAs is really a suggestion that FDA has failed to properly segregate, the Court concludes that defendants have satisfied their segregability requirements. See infra at 17-19.

broader category of information referencing specific pending ANDAs and their contents. Judicial Watch, Inc. v. FDA, 449 F.3d at 148-49; Appleton v. FDA, 451 F. Supp. 2d at 141-142 n. 7. That whole paragraphs have been redacted in some documents does not alone demonstrate improper withholdings.

2. Incoming Correspondence

ViroPharma takes issue with FDA's withholding of incoming correspondence from drug manufacturers and other members of the industry that relate to the bioequivalence standard for vancomycin. Pl. Reply at 4. For some of this correspondence, FDA has stated in one of its declarations that "[t]he inquiries about the bioequivalence requirements . . . are intertwined with other information about the inquiring entity and its proposed product." Sadler Decl. Reply ¶ 19 (discussing *Vaughn* index Nos. 908, 960 & 961). For other incoming correspondence, FDA claims that the information need not be released because the documents are nonresponsive. Def. Reply at 24-34; see e.g., Sadler Decl. Reply ¶¶ 17-19.

Where documents reference pending ANDAs, FDA has properly redacted this information, see supra at 8-10, and has also demonstrated that it has segregated non-exempt information. See infra at 17-19. To the extent that the incoming correspondence discusses drug products other than vancomycin, see Def. Reply at 25, it is nonresponsive and FDA is not required to release it. But with regard to the portions of documents that discuss FDA's bioequivalence recommendations for vancomycin generally without reference to a drug manufacturer's pending ANDA filing, FDA must produce this information so long as it is segregable from the properly exempt information. Such information is responsive to

ViroPharma's FOIA request, which must be read broadly. See Milner v. Department of the Navy, 131 S. Ct. 1259, 1265 (2011) (FOIA strongly favors openness and "'broad disclosure'" with narrowly construed exemptions). The Court therefore will require FDA to supplement its declarations and *Vaughn* index to establish whether any requests for information on bioequivalence recommendations for vancomycin by drug manufacturers in their incoming correspondence can be segregated from the properly exempt information. See Sadler Decl. Ex. C (*Vaughn* index Nos. 2, 9-10, 92-93, 95, 178, 197-99, 208-09, 235, 271-73, 282, 282, 355, 390, 397-403, 407, 409, 424, 434, 442-47, 465, 474-75, 481-83, 489, 493, 499, 504, 906-08, 960-63, 1197-98 & 1200-02).

B. Exemption 5

FOIA Exemption 5 protects from disclosure "inter-agency or intra-agency memorandums or letters which would not be available by law to a party . . . in litigation with the agency." 5 U.S.C. § 552(b)(5); see Ancient Coin Collectors Guild v. Department of State, 641 F.3d 504, 512 (D.C. Cir. 2011). It "incorporates the traditional privileges the Government could assert in civil litigation against a private litigant — including . . . the attorney-client privilege, the work product privilege, and the deliberative process privilege — and excludes these privileged documents from FOIA's reach." Loving v. Dep't of Defense, 550 F.3d 32, 37 (D.C. Cir. 2008) (internal quotations omitted); see also Wilderness Soc. v. Department of Interior, 344 F. Supp. 2d 1, 9 (D.D.C. 2004); Defenders of Wildlife v. Department of Agriculture, 311 F. Supp. 2d 44, 57 (D.D.C. 2004). ViroPharma disputes FDA's withholdings under Exemption 5's deliberative

process privilege with respect to three groups of documents: draft documents; internal review documents; and laboratory data.[6]

The deliberative process privilege protects agency documents that are both predecisional and deliberative. Ancient Coin Collectors Guild v. Department of State, 641 F.3d at 512; Judicial Watch, Inc. v. FDA, 449 F.3d at 151. A document is "predecisional" if it was generated before the agency action was finally adopted, and "deliberative" if it "reflects the give-and-take of the consultative process." Public Citizen, Inc. v. OMB, 598 F.3d 865, 874 (D.C. Cir. 2010) (internal quotations omitted). The deliberative process privilege encourages open, frank discussions by agency policy makers, protects against premature disclosure of proposed policies before they are finally adopted, and protects against confusing the issues and misleading the public about reasons and rationales that, in the end, were not in fact among the grounds for decision. See id.; Appleton v. FDA, 451 F. Supp. 2d at 142.

1. Draft Documents

The FDA has withheld draft versions of numerous documents under the deliberative process privilege. While acknowledging that the deliberative process may be protected, ViroPharma argues that FDA must provide the factual content and recitations of past final agency decisions that are contained within the drafts. Pl. Reply at 15-18.

---

[6] FDA has withheld several documents under the attorney work-product privilege and the attorney-client privilege. See 5 U.S.C. § 552(b)(5); Def. Mot. at 19-22. ViroPharma does not dispute the validity of these withholdings, and the Court concludes that FDA has demonstrated that the redactions are appropriate under Exemption 5. Consequently, the Court will grant defendants' motion for summary judgment with respect to the redactions under the work-product and attorney-client privileges.

Although there is a longstanding distinction between factual and deliberative materials under Exemption 5, see Goodrich Corp. v. EPA, 593 F. Supp. 2d 184, 189 (D.D.C. 2009) (citing EPA v. Mink, 410 U.S. 73, 79 (1973)), ViroPharma is incorrect when it argues that FDA must segregate and disclose the factual background and recitations of past agency final decisions from the draft documents in this case. "Exemption 5 was intended to protect not simply deliberative *material*, but also the deliberative *process* of agencies." Montrose Chemical Corp. v. Train, 491 F.2d 63, 71 (D.C. Cir. 1974) (emphasis added). Thus, "in some cases selection of facts or summaries may reflect a deliberative process which exemption 5 was intended to shelter." Id.; see also Mead Data Cent., Inc. v. Department of the Air Force, 566 F.2d 242, 256 (D.C. Cir. 1977) ("In some circumstances, . . . the disclosure of even purely factual material may so expose the deliberative process within an agency that it must be deemed exempted[.]").

The choice of what factual material and prior final agency opinions to include or remove during the drafting process is itself often part of the deliberative process, and thus is properly exempt under Exemption 5. See Reliant Energy Power Generation, Inc. v. FERC, 520 F. Supp. 2d at 204 ("'[D]isclosure of editorial judgments — for example, decisions to insert or delete material or to change a draft's focus or emphasis — would stifle the creative thinking and candid exchange of ideas[.]'") (quoting Dudman Commc'ns Corp. v. Department of the Air Force, 815 F.2d 1565, 1569 (D.C. Cir. 1987)). In Goodrich Corp. v. EPA, 593 F. Supp. 2d 184 (D.D.C. 2009), for example, Judge Bates permitted the EPA to withhold the factual content and data contained within a draft model under Exemption 5 because "evolving iterations of the model's inputs and calibration reflect the opinions of the staff currently developing the model,

which may not represent EPA's ultimate opinions relating to these matters. . . . [E]ven if the data plugged into the model is itself purely factual, the selection and calibration of data is part of the deliberative process to which Exemption 5 applies." Id. at 189. The Court is persuaded by the defendants' submission that such is the case here.

ViroPharma relies on Brinton v. Department of State, 636 F.2d 600 (D.C. Cir. 1980), in which the court of appeals stated that "Exemption 5 does not protect final statements of policy or final actions of agencies." Id. at 605. The court in Brinton, however, was referring to documents that were *themselves* final agency opinions, not recitations of final opinions contained within subsequent deliberative recommendations. Indeed, the documents in question in Brinton were properly withheld under Exemption 5, and the court did not require any portions of them to be segregated. Id. ("The requested documents in this case, however, bear no indicia of finality.").

2. Internal Review Documents

"Purely factual material usually cannot be withheld under Exemption 5 unless it reflects an 'exercise of discretion and judgment calls.'" Ancient Coin Collectors Guild v. Department of State, 641 F.3d at 513 (quoting Mapother v. Department of Justice, 3 F.3d 1533, 1539 (D.C. Cir. 1993)). While factual material need not be segregated from draft documents because the choice to include or remove such material in each draft reflects the agency's deliberative process, see supra at 13-14, this rationale does not apply to internal documents generally. But where factual material is "assembled through an exercise of judgment in extracting pertinent material from a vast number of documents for the benefit of an official called upon to take discretionary action[,]" the information may be withheld. Ancient Coin Collectors

Guild v. Department of State, 641 F.3d at 513 (quoting Mapother v. Department of Justice, 3 F.3d at 1539).

ViroPharma requests that the factual information and recitations of settled agency policy that are contained in internal review documents be segregated and released. Pl. Reply at 12-13. For the reasons previously discussed, the majority of these documents are properly redacted under Exemption 5 as part of the deliberative process, see Sadler Decl. Ex. C (*Vaughn* index Nos. 295, 318, 414, 415, 645 & 646); supra at 13-14, or under Exemption 4 because they reference pending ANDAs. See Sadler Decl. Ex. C (*Vaughn* index Nos. 498, 510, 522, 523, 645, 646 & 905); supra at 8-10. But one portion of one document is redacted because it contains a summary of the regulatory background of vancomycin, although it does not appear to be a draft. See Sadler Decl. Ex. C (*Vaughn* index No. 235). In addition, ViroPharma singles out four documents from the medical officer's review of pending ANDAs that ViroPharma contends are withheld in full. Pl. Reply at 12. The justification for withholding these documents is that they contain internal deliberations and reference pending ANDAs. Sadler Decl. Ex. C (*Vaughn* index Nos. 495, 497, 507 & 509).

In reviewing defendants' *Vaughn* index and declarations, the Court cannot discern whether factual portions of these internal review documents were or were not withheld in full or were provided in redacted form. The Court therefore will require FDA to supplement its declarations and *Vaughn* index to establish whether factual portions of non-draft review documents were redacted and why they were redacted; or, if they were withheld in full, why they cannot be provided in redacted form. See Sadler Decl. Ex. C. (*Vaughn* index Nos. 235, 495, 497, 507 & 509).

In addition, ViroPharma asserts that FDA withheld a paragraph of a 2006 review document that contains FDA control numbers of incoming communications, which ViroPharma wishes to review in order to determine the number of letters submitted to FDA. Pl. Reply at 14 (referencing *Vaughn* index Nos. 295, 318, 414-15, & 645-46). The Court cannot discern, from the *Vaughn* index and the parties' filings, whether the documents ViroPharma points to contain the withheld paragraph, or for what reason FDA is claiming the information should be withheld. The Court therefore also will require FDA to supplement its *Vaughn* index and declaration with respect to Nos. 295, 318, 414-15, and 645-46.

3. Laboratory Data

Finally, ViroPharma objects to FDA withholding laboratory data contained within records prepared to assist the agency's development of its bioequivalence recommendations. Def. Reply at 21; Pl. Reply at 18; Sadler Decl. Ex. C (*Vaughn* index Nos. 46, 48, 53, 54). ViroPharma argues that the laboratory data must be segregated from the sections containing deliberations and must be released. It cites Bristol-Myers Co. v. FTC, 424 F.2d 935 (D.C. Cir. 1970), which states that "*[p]urely* factual reports and scientific studies cannot be cloaked in secrecy by an exemption designed to protect . . . internal working papers in which opinions are expressed[.]" Id at 939 (emphasis added) (internal quotations omitted). That case is not directly on point, however, because the preliminary reports that ViroPharma requests are not *purely* factual reports, but contain the internal deliberations of the FDA, including the analysis of the data found in those studies. Sager Decl. Reply ¶ 16.

Defendants argue "that preliminary scientific data are properly part of an agency's deliberative process[.]" Def. Reply at 21. Defendants cite Chemical Manufacturers Ass'n v. Consumer Product Safety Commission, 600 F. Supp. 114 (D.D.C. 1984), for the proposition that preliminary scientific data generated in connection with an ongoing policy deliberation may properly be withheld under Exemption 5. Id. at 118. ViroPharma responds that the laboratory data cannot be withheld because deliberations are no longer ongoing, the reports were prepared for a 2009 dissolution study, and the study has now been released. Pl. Reply at 20.

It is not clear to the Court what bioequivalence recommendation the reports were prepared for. FDA merely states that the records were prepared "in the course of [FDA's] development of a bioequivalence recommendation[.]" Sager Decl. Reply ¶ 16. The Court therefore will require FDA to supplement its *Vaughn* index and declarations to establish which bioequivalence recommendation the laboratory results were originally prepared for and why the documents are properly withheld. See Sadler Decl. Ex. C. (*Vaughn* index nos. 46, 48, & 53-54).

C. Segregability

Under the FOIA, "[a]ny reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt." 5 U.S.C. § 552(b). "'It has long been the rule in this Circuit that non-exempt portions of a document must be disclosed unless they are inextricably intertwined with exempt portions.'" Wilderness Soc. v. Department of Interior, 344 F. Supp. 2d at 18 (quoting Mead Data Cent., Inc. v. Department of Air Force, 566 F.2d at 260); see also Zavala v. Drug Enforcement Admin., 667 F. Supp. 2d 85, 102 (D.D.C. 2009). And the agency has "the burden of demonstrating that

[the] withheld documents contain no reasonably segregable factual information." Mokhiber v. Department of the Treasury, 335 F. Supp. 2d 65, 68-69 (D.D.C. 2004). "The adequacy of the *Vaughn* index in regard to the segregability question turns on whether the agency has sufficiently explained why there was no reasonable means of segregating factual material from the claimed privileged material." Wilderness Soc. v. Department of Interior, 344 F. Supp. 2d at 18. "[A] blanket declaration that all facts are so intertwined to prevent disclosure under the FOIA does not constitute a sufficient explanation of non-segregability." Id. at 19; see Barnard v. Department of Homeland Sec., 531 F. Supp. 2d 131, 140 (D.D.C. 2008).

Defendants argue that they have satisfied their segregability obligations because all records responsive to ViroPharma's request were reviewed "line-by-line" and the agency redacted only portions of documents where appropriate. Def. Mot. at 27-28. Regardless of whether a declaration that an agency conducted a "line-by-line" search is sufficient to satisfy an agency's obligations in and of itself, compare Elec. Privacy Info. Ctr. v. Transp. Safety Admin., Civil Action No. 03-1846, 2006 WL 626925, at *8 (D.D.C. Mar. 12, 2006) (finding that an avowal of a "line-by-line" search is not determinative as to whether the agency satisfied its segregability obligations), with Perry-Torres v. Department of State, 404 F. Supp. 2d 140, 144 (D.D.C. 2005) ("At a minimum, the explanation should state that a line-by-line analysis of each document was conducted[.]"), a statement representing that a "line-by-line" search was conducted along with a sufficiently detailed *Vaughn* index and declarations enumerating the reasons why each document was properly withheld is "sufficient to fulfill the agency's obligation" regarding segregability. Elec. Privacy Info. Ctr. v. Transp. Safety Admin., 2006 WL 626925, at *8 (quoting Johnson v. Executive Office for United States Attorneys, 310 F.3d 771,

776 (D.C. Cir. 2002)). Having reviewed the *Vaughn* index and the declarations submitted by the defendants, the Court concludes that, except as discussed supra at 10-11, 15-17, defendants have satisfied their segregability obligations for all documents that they have withheld or withheld in part under an enumerated exemption.

D. In Camera Review and Bad Faith

In support of its motion for *in camera* review, ViroPharma's central argument is that FDA has acted in bad faith in replying to ViroPharma's FOIA request. For this argument, ViroPharma relies primarily on FDA's rolling release of documents during the course of this litigation. Pl. Reply at 21-22. The argument that such a rolling release indicates bad faith has been "emphatically reject[ed]" by the D.C. Circuit. Meeropol v. Meese, 790 F.2d 942, 953 (D.C. Cir. 1986) (quoting Military Audit Project v. Casey, 656 F.2d at 754). It is established that "continuing discovery and release of documents . . . *shows good faith* on the part of the agency that . . . continues to search for responsive documents." Landmark Legal Foundation v. EPA, 272 F. Supp. 2d 59, 63 (D.D.C. 2003) (citing Meeropol v. Meese, 790 F.2d at 952-53) (emphasis added). Accepting ViroPharma's argument "would work mischief in the future by creating a disincentive for an agency to reappraise its position, and when appropriate, release documents previously withheld." Meeropol v. Meese, 790 F.2d at 953 (quoting Military Audit Project v. Casey, 656 F.2d at 754).

ViroPharma argues that supplemental releases may indicate bad faith if supported by other evidence. Pl. Reply at 21. The "other evidence" ViroPharma points to is that, after one set of documents was released, FDA expressed to ViroPharma that it was "confident" that it had

met its obligations but then, months later, released another set of documents. Pl. Reply at 21. ViroPharma's argument is unpersuasive. After an agency has released documents, it is certainly reasonable for it to believe it has met its FOIA obligations. FDA's statement was not an indication that FDA would not continue to respond to ViroPharma's inquiries. Indeed, after the initial release, the parties continued to correspond with each other and to litigate this case, leading to the further release of documents. This is exactly what the good faith presumption for subsequent releases is meant to encourage.

As ViroPharma acknowledges, *in camera* review is committed to the discretion of the district court. See Juarez v. Department of Justice, 518 F.3d 54, 59-60 (D.C. Cir. 2008); Quinon v. FBI, 86 F.3d 1222, 1227 (D.C. Cir. 1996). While the FOIA provides district courts the "option" to conduct *in camera* review, "it by no means compels the exercise of that option." Juarez v. Department of Justice, 518 F.3d at 60. The Court, in its discretion, does not find any basis to conduct an *in camera* review in this case. The Court therefore will deny ViroPharma's request.[7]

[7] ViroPharma has provided the Court with a notice of supplemental authority [Dkt. No. 39]. ViroPharma provides documents relating to an FDA employee who allegedly engaged in insider trading and documents, which, it asserts, indicate that FDA did not locate all relevant documents. The first set of documents have no bearing on this case; the individual FDA employee had no involvement in FDA's vancomycin approval process. The second set of documents is not supplemental at all; the documents are several years old and already before the parties and the Court.

IV. CONCLUSION

For the foregoing reasons, the Court will require defendants to supplement the *Vaughn* index and declarations with respect to *Vaughn* index Nos. 2, 9-10, 46, 48, 53-54, 92-93, 95, 178, 197-99, 208-09, 235, 271-73, 282, 282, 295, 318, 355, 390, 397-403, 407, 409, 414-15, 424, 434, 442-47, 465, 474-75, 481-83, 489, 493, 495, 497, 499, 504, 507, 509, 645-46, 906-08, 960-63, 1197-98, and 1200-02. Defendants' motion for summary judgment will be granted with respect to all other documents and denied without prejudice with respect to the above listed documents. Plaintiff's motion for summary judgment and motion for *in camera* review will be denied. An Order consistent with this Opinion shall issue this same day.

SO ORDERED.

/s/
PAUL L. FRIEDMAN
United States District Judge

DATE: March 16, 2012