NOT FOR PUBLICATION

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Goldwater Institute, Plaintiff, v. United States Department of Health and Human Services, Defendant.	No. CV-15-01055-PHX-SRB **ORDER**

Plaintiff Goldwater Institute ("Plaintiff") brought this Freedom of Information Act matter after Defendant United States Department of Health and Human Services ("Defendant" or "HHS") denied Plaintiff's FOIA request for records from the United States Food and Drug Administration ("FDA"). The Court has twice denied summary judgment and ordered Defendant to submit *Vaughn* indices of withheld documents. The parties have submitted a third round of summary judgment briefing, on which the Court heard oral argument on December 4, 2018. (Doc. 84, Minute Entry.) The Court now resolves Plaintiff's Third Motion for Summary Judgment ("PMSJ") (Doc. 73) and Defendant's Renewed Motion for Summary Judgment ("DMSJ") (Doc. 77).

I. BACKGROUND

The Court has previously summarized the factual background of this case:

> On August 7, 2014, Plaintiff submitted a Freedom of Information Act ("FOIA") request to the United States Food and Drug Administration ("FDA") seeking
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> > Any and all records that indicate the approval process, deliberations made during that process,

> and final approval records regarding provision or approval of the drug and serum "ZMapp" to be administered to Dr. Kent Brantly and Ms. Nancy Writebol, or any other individuals suspected to be infected with the Ebola virus, under the "compassionate use" process or any other approval process at the FDA.

FDA referred Plaintiff's FOIA request to the Division of Information Disclosure Policy ("DIDP") because ZMapp is regulated by the Center for Drug Evaluation and Research. ZMapp is a biological product that has an active Investigational New Drug application ("IND") but no approved Biologics Licensing Application ("BLA"). DIDP examined the FOIA request and determined that Plaintiff sought records contained in INDs, the disclosure of which is prohibited by FDA regulations unless they have been publicly disclosed or acknowledged by their sponsor. On September 29, FDA denied Plaintiff's FOIA request because it "sought trade secrets and [confidential commercial information ("CCI")] exempt from disclosure under FOIA Exemption 4," as well as FDA regulations and the Federal Trade Secrets Act. Plaintiff appealed FDA's denial to HHS on October 23. On February 19, 2015, HHS denied Plaintiff's FOIA appeal citing FOIA Exemptions 3, 4, 5, and 6, as well as the aforementioned FDA regulations governing IND disclosure.

After Plaintiff filed this case, FDA became aware that Dr. Brantley and Ms. Writebol had publicly disclosed their receipt of three doses of ZMapp. On November 24, 2015, FDA provided Plaintiff copies of the two emails authorizing Dr. Brantly's and Ms. Writebol's expanded access INDs to proceed because the report was drafted by the two patients and ZMapp's physician-sponsor. FDA also produced three documents describing the agency's general process for authorizing expanded access INDs for treatment of individuals in emergency situations. The agency continued, however, in its refusal to disclose records of its deliberations concerning authorization, as well as a third expanded access IND authorization.

On June 16, 2016, the Court ordered Defendant to submit a *Vaughn* index of withheld records to determine whether Defendant properly invoked the above-referenced FOIA exemptions and if any documents contained in nine volumes of responsive records withheld in its initial denial can be segregated from the exempted documents. Defendant submitted two indices describing the records withheld and stating the basis for withholding each. Because the descriptions in the second *Vaughn* index revealed the existence of a third expanded access IND, Defendant deemed the email authorization "available for public disclosure" and released it on November 24, 2016.

(Doc. 66, Jan. 24, 2018 Order at 1–3 (citations and footnotes omitted).)[1]

After a second round of briefing, the Court ordered Defendant to submit a revised, consolidated *Vaughn* index that addressed certain concerns. First, the Court ordered Defendant to disclose several responsive documents previously labeled as nonresponsive, or else demonstrate their exemption. (*Id.* at 9–10.) Second, the Court ordered Defendant to provide better descriptions to allow the Court to resolve the segregability of nonexempt information from otherwise-exempt documents. (*Id.* at 11–12.) Finally, to avoid the possible overinclusion of documents in the IND file, the Court ordered Defendant to "(1) identify[] the agency policy or guidelines defining the components of an IND file, (2) indicat[e] which records withheld here are considered a part of the IND file, and (3) justify[] its placement of those particular documents in the IND file." (*Id.* at 12.) Defendant filed a Revised, Consolidated *Vaughn* Index ("RCVI") (Doc. 69-2) on March 8, 2018, and the parties later cross-moved for summary judgment.

II. LEGAL STANDARD & ANALYSIS

The Freedom of Information Act ("FOIA") requires government agencies to make certain information about their activities available to the public. *See* 5 U.S.C. § 552. "The FOIA embodies a strong federal policy in favor of full agency disclosure of government documents. Any inquiry under the Act thus begins with a strong presumption in favor of disclosure." *Church of Scientology Int'l v. U.S. I.R.S.*, 995 F.2d 916, 919 (9th Cir. 1993) (internal quotations omitted). "The [FOIA] contains nine exemptions to its general policy mandating the broad disclosure of government documents. These nine exemptions are to be narrowly construed by the courts." *GC Micro Corp. v. Def. Logistics Agency*, 33 F.3d 1109, 1112 (9th Cir. 1994). An agency may withhold a requested document "only if the

[1] The emails authorizing Dr. Brantly's and Ms. Writebol's expanded access INDs contained the following identical language:

> We have reviewed your emergency IND request and have granted the use of ZMapp for this patient. IND 123,630 has been assigned to this request. Please let us know if you have any additional questions or concerns.

(Jan. 24, 2018 Order at 2 n.2.)

material at issue falls within one of the nine statutory exemptions." *Maricopa Audubon Soc'y v. United States Forest Serv.*, 108 F.3d 1082, 1085 (9th Cir. 1997). The burden is on the agency to show that withheld materials are exempt from disclosure. § 552(a)(4)(B); *see also Minier v. CIA*, 88 F.3d 796, 800 (9th Cir. 1996). Courts may rely solely on government affidavits in resolving FOIA cases. *Lion Raisins, Inc. v. USDA*, 354 F.3d 1072, 1082 (9th Cir. 2004).

The cross-motions concern 60 records listed in Defendant's latest *Vaughn* index. (*See* PMSJ at 14.) Plaintiff makes five arguments for their disclosure. First, Plaintiff maintains that the Court's last Order belies Defendant's continued view that records regarding personal importation of ZMapp are nonresponsive. (*Id.* at 4–6.) Second, Plaintiff argues that other records related to IND timing and approval are likewise responsive and subject to disclosure. (*Id.* at 6–8.) Third, Plaintiff challenges Defendant's reliance upon FDA regulations governing disclosure of IND file contents. (*Id.* at 8–11.) Fourth, Plaintiff questions the deliberative nature of three records concerning the FDA's evaluation of an expanded access IND. (*Id.* at 11–13; *see also* RCVI at 17 (line 31), 19 (lines 35–36).) Finally, Plaintiff remains insistent that responsive information is segregable from any otherwise-exempt records. (PMSJ at 13–14.) The third is dispositive.

The Court's previous Order provides a useful starting point. There the Court found that, per FDA regulations implementing Exemption 4, Defendant had properly withheld all *legitimate* IND file contents. (*See* Jan. 24, 2018 Order at 5–6, 12.) Uncertain about the file's proper composition, however, the Court ordered Defendant to supplement its *Vaughn* index accordingly. (*Id.* at 12.) As expected, Defendant considers all withheld records to be a part of the IND file. If Defendant is correct, the analysis ends there. (*See id.*) That is the law of the case.[2] *See United States v. Phillips*, 367 F.3d 846, 856 (9th Cir. 2004).

A. Agency Policy Governing IND Files

[2] Plaintiff neither acknowledges the Court's earlier finding nor offers a basis for departing from it. *See United States v. Alexander*, 106 F.3d 874, 876 (9th Cir. 1997) (listing circumstances warranting departure from law of the case). The Court nevertheless addresses Plaintiff's continued argument against the FDA's reliance on regulations governing the disclosure of information contained in IND files.

Plaintiff does not immediately question the placement of specific records in the IND file.[3] Plaintiff instead focuses on Defendant's reliance on regulations governing their disclosure—namely, by accusing Defendant of undermining the FOIA with its "broad and unilateral policy" governing IND files. (PMSJ at 8.)

The first example of such subversion, Plaintiff argues, is DIDP Director Nancy Sager's declaration. (*Id.*) By describing the latest *Vaughn* index in the first person—for instance, explaining "the reason(s) why I consider each email to be a part of the expanded access IND file"—Director Sager ostensibly considers herself the sole authority on IND file contents. (*See id.* (citing Doc. 69-1, Sixth Decl. of Nancy B. Sager ("Decl.") ¶ 5).) Far from it. As its name suggests, a declaration tends to bear the voice of its declarant. Meanwhile, a closer look reveals that Director Sager specifies which policies govern IND files and how she believes they apply here. (*See* Decl. ¶¶ 7–13.) Precisely what the Court ordered.

Plaintiff next takes aim at the regulations themselves. Plaintiff argues that the FDA is using its own regulations and internal policies to undo the will of Congress by expanding the limited exemptions to the FOIA. (*See* PMSJ at 9–10.) Of course, agencies may not unilaterally determine their FOIA obligations. *See Lessner v. U.S. Dep't of Commerce*, 827 F.2d 1333, 1335 (9th Cir. 1987) ("A basic policy of FOIA is to ensure that Congress and not administrative agencies determines what information is confidential."). But that is not what the FDA is doing—at least not this time. *Cf. Teich v. FDA*, 751 F. Supp. 243, 249 (D.D.C. 1990) (rejecting FDA "presubmission review" regulations as "nothing more than an attempt to get around the FOIA").

Consider the relevant regulatory landscape. Per Exemption 4, FOIA does not require disclosure of "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). FDA regulations implementing Exemption 4 similarly provide that "[d]ata or information submitted or

[3] To the extent Plaintiff does question the IND file's composition, it relies on briefing submitted in support of its original summary judgment motion. (*See* PMSJ at 9 (citing briefing in arguing that "the regulations the FDA is relying on do not apply to the records sought in this case").

divulged to the [FDA] which fall within the definitions of a trade secret or of confidential commercial or financial information are not available for public disclosure." 21 C.F.R. § 20.61(c); *see also* § 20.61(a), (b) (defining "trade secret" and "commercial or financial information that is privileged or confidential").[4] Such a designation "expire[s] 10 years after the records were submitted to the [FDA]." § 20.61(d). The FDA also regulates experimental drugs pursuant to the Food, Drug, and Cosmetic Act of 1938 ("FDCA").[5] The regulations pertinent here govern INDs, which provide for the investigation of an experimental drug's safety and effectiveness. *See* 21 U.S.C. § 355(i); 21 C.F.R. § 312.1 *et seq.* These regulations prohibit the disclosure of even the existence of an IND before it is "publicly disclosed or acknowledged." 21 C.F.R. §§ 312.130(a), 601.50(a).[6] In the event of such a pre-license disclosure, "no data or information contained in the [IND] file is available for public disclosure before such license is issued." § 601.51(d)(1). Once a license issues, much of the IND file's contents—save certain proprietary information—"are immediately available for public disclosure unless extraordinary circumstances are shown." § 601.51(e), (f).

Plaintiff argues that Defendant is using this scheme to expand the FOIA's narrow statutory exceptions. Indeed, Plaintiff contends that other courts have already rejected similar attempts to withhold IND file contents. (PMSJ at 10–11.) Not quite.

Plaintiff first points to *Government Accountability Project v. U.S. Department of Health and Human Services*.[7] That case, like this one, involved a FOIA request to the FDA. And the similarities end there. HHS did raise some of the same regulations it does here, but not to prevent disclosure. *See* 691 F. Supp. 2d at 176 ("At no point . . . do Defendants argue that the information at issue in this case is subject to these specific regulatory provisions . . . ."). Another, albeit unrelated regulatory compliance question was also "not

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[4] The Trade Secrets Act criminalizes the disclosure of such information by an FDA employee. *See* 18 U.S.C. § 1905.
[5] 21 U.S.C. §§ 301–397.
[6] *See also* 21 C.F.R. § 312.130(b) ("The availability for public disclosure of all data and information in an investigational new drug application for a biological product will be governed by the provisions of §§ 601.50 and 601.51.").
[7] 691 F. Supp. 2d 170 (D.D.C. 2010).

presently before the Court." *Id.* at 177. The irrelevance of these regulations was not, as Plaintiff suggests, a matter of invalidity, but of non-reliance. *See id.* at 176 ("Careful review . . . makes clear that Defendants do *not* affirmatively rely on these provisions to justify the withholdings at issue."). No analogous omission arose here.

Plaintiff's reliance on *Teich* is similarly misplaced. There the district court rejected the FDA's use of a "presubmission review" regulation that allowed regulatees to file documents with the FDA without fear of FOIA-mandated disclosure. *See* 751 F. Supp. at 246. The agency did this by first determining which of the filed documents were exempt from the FOIA, then allowing regulatees to withdraw any unprotected documents without them becoming "agency records." *See id.* at 246–47. Only one problem: the Supreme Court had already defined the term to include any document created or obtained by an agency in performing its official duties. *Id.* at 248 (citing *U.S. Dep't of Justice v. Tax Analysts*, 492 U.S. 136, 144–46 (1989)). Once the documents were filed, they became agency records subject to the FOIA. *See id.* The present arrangement, by contrast, scarcely "forge[s] a Northwest passage around the FOIA." *See id.* at 247. Neither the FOIA nor the FDCA regulations engage in the sort of semantic parlor games seen in *Teich*. No redefinition of well-established terms; no agenda to completely dodge the FOIA. Quite the contrary, in fact. The present arrangement explicitly anticipates the public disclosure of the information it covers. *See* 21 C.F.R. §§ 20.61(d), 601.51(e), (f).

This eventuality apparently sufficed in *R&D Laboratories, Inc. v. FDA*.[8] There the FDA denied a FOIA request for the contents of a pending NDA. *See* 2000 U.S. Dist. LEXIS 20209, at *13. Although without explicitly invoking the scheme at issue, the FDA argued—and the court agreed—that "while the unapproved application is pending it is confidential *in toto*." *Id.*, at *18; *see also* 21 C.F.R. §§ 314.430(d)(1), 601.51(d)(1). Consistent with Exemption 4, the court found that requiring the FDA to produce so much as a *Vaughn* index would harm competition and "would frustrate the Government's gathering of information for review in the future." *R&D Labs.*, 2000 U.S. Dist. LEXIS 20209, at **18–19; *accord*

[8] No. 00-cv-0165 (JLG), 2000 U.S. Dist. LEXIS 20209 (D.D.C. Sept. 7, 2000).

GC Micro Corp., 33 F.3d at 1112–13 ("Information qualifies as 'confidential' for the purposes of Exemption 4 if disclosure is likely to have either of the following effects: (1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained.") (quotation and citation omitted). Such a rule did not undermine the FOIA. The requester was still entitled to application information, just after an approval decision. *See R&D Labs.*, 2000 U.S. Dist. LEXIS 20209, at *19.

So too here. The Court detects no meaningful distinction between the application file in *R&D Laboratories* and this one. Both contain important developmental, compositional, safety, and manufacturing data, the revelation of which before a licensing decision would likely impede future candor on the part of submitting entities. *See id.*, at *18; *see also Judicial Watch, Inc. v. FDA*, 449 F.3d 141, 148–49 (D.C. Cir. 2006) (observing FDA "incentive to be a good steward" with application file information).[9] Of course the calculus changes after a licensing decision. A renewed FOIA request can be made then, at which point the FDA will, per its own regulations, be required to justify any continued withholdings by some other means. *See* 21 C.F.R. § 601.51(d)(1); *R&D Labs.*, 2000 U.S. Dist. LEXIS 20209, at *19. Until that time, though, Exemption 4 extends to the IND file, and the Court's earlier finding stands.[10] *See Alexander*, 106 F.3d at 876.

B. Records in the ZMapp IND File

[9] While the D.C. Circuit determined that "Exemption 4 extends to at least some information contained in INDs and NDAs," it ultimately found that such information is not "categorically exempt" from disclosure. *Judicial Watch*, 449 F.3d at 148, 149. The Court is less certain. First, *Judicial Watch* did not address the regulatory scheme raised here. *See id.* at 148–50. Second, the court based this conclusion on an earlier, distinguishable decision. *Id.* at 149 (citing *Public Citizen Health Research Grp. v. FDA*, 185 F.3d 898, 906 (D.C. Cir. 1999)). *Public Citizen* concerned a FOIA request for information in an abandoned drug application and, like *Judicial Watch*, also did not address the regulations that the FDA invokes here. *See* 185 F.3d at 901. The Court therefore gleans little guidance from either decision. *Accord R&D Labs.*, 2000 U.S. Dist. LEXIS 20209, at **17–18 (distinguishing *Public Citizen*).

[10] Such a per se exemption, while uncommon, is not unprecedented. *See, e.g., F.T.C. v. Grolier Inc.*, 462 U.S. 19, 28 (1983) (permitting categorical withholding of attorney work product under Exemption 5); *Wiener v. F.B.I.*, 943 F.2d 972, 978 n.5 (9th Cir. 1991) (recognizing that an "entire class" of requested documents could be "*per se* exempt from disclosure regardless of the content of each withheld document") (citing *Lewis v. I.R.S.*, 823 F.2d 375, 380 (9th Cir. 1987)), *cert. denied*, 505 U.S. 1212 (1992).

Defendant still must justify the IND file's contents. *See Public Citizen*, 185 F.3d at 904. Along with its revised *Vaughn* index, Defendant included a declaration from Ms. Sager detailing the policies governing IND files. She explains that in addition to CCI, the IND file also contains private information regarding study participants, correspondence and other sponsor communications, and scientific reviews. (Decl. ¶ 7.) Email communications—whether internal discussions among reviewers or between the agency and a sponsor—are also included. (Decl. ¶ 8.)

Ms. Sager cites two pieces of guidance to explain the FDA's approach. (*See* Decl. ¶¶ 9–11.) First, FDA regulations define "administrative file" as "the file or files containing all documents pertaining to a particular administrative action, including internal working memoranda, and recommendations." 21 C.F.R. § 10.3(a). An "administrative action" encompasses "every act, including the refusal or failure to act, involved in the administration of any law by the Commissioner." *Id.* Though not expressly contemplated by regulation, Ms. Sager understands the approval (or not) of an IND or NDA to be an administrative action. (*See* Decl. ¶ 9.) As such, the agency considers the documents at issue—all of which pertain to a still-pending action—to be part of the IND file. (*See id.* (citing 21 C.F.R. §§ 312.130, 601.50, and 601.51(a)).) Second, Ms. Sager points to the CDER Program Records Control Schedule ("PRCS") (Doc. 70). (*See* Decl. ¶ 10.) The PRCS lists a similarly broad range of records that make up an IND file, including "correspondence" and "other related materials." (*See* PRCS at 1, 4.)

Plaintiff advances a more limited view. (*See* PMSJ at 9 (citing Doc. 25, Mem. in Supp. of Pl's Resp. to Def.'s Mot. for Summary J. & Pl.'s Cross-Mot. for Summary J. ("Mem.") at 8–9).) Applicable regulations define the "biological product file" as "all data and information submitted with or incorporated by reference in any application for a biologics license, IND's incorporated into any such application, master files, and other related submissions." 21 C.F.R. § 601.51(a). Seizing upon the term "submissions," Plaintiff maintains that the IND file includes "information *provided to* the agency, not information or records *created by* the agency." (Mem. at 9.) Because the emails were

generated within the agency, they cannot be part of the file—or so the argument goes.

Plaintiff's distinction proves illusory. Even if the file may only include information provided to the agency, it follows that emails discussing that information, even if only within the agency, must be included as well. This is consistent with the FOIA's information-document distinction. *See ACLU of N. Cal. v. U.S. Dep't of Justice*, 880 F.3d 473, 489 (9th Cir. 2018) (observing that "the focus of the FOIA is information, not documents") (quotation and modification omitted). Plaintiff's approach, conversely, would make it impossible for the agency to discuss records in an IND file without simultaneously forfeiting the confidentiality of the information they contain. There is no reason to believe the FDA designed § 601.51(a) to force such a false choice. In fact, at least one court in this circuit has understood an analogous regulation to include "internal FDA memoranda and other correspondence" in a drug application file. *See Citizens Comm'n on Human Rights v. FDA*, No. 92CV5313, 1993 WL 1610471, at *2 (C.D. Cal. May 10, 1993) (referring to 21 C.F.R. § 314.430), *aff'd in part, remanded in part*, 45 F.3d 1325 (9th Cir. 1995). This, too, is the Court's view.

The term "other related submissions" hardly forecloses the inclusion of inter- and intra-agency emails in an IND file. Lacking a precise definition or illustrative examples, the term is arguably ambiguous. *See Marsh v. J. Alexander's LLC*, 905 F.3d 610, 624 (9th Cir. 2018) (finding regulatory term ambiguous given absence of precise definition or useful examples). If so, the FDA's interpretation remains reasonable. *See id.* (deferring to agency interpretation of regulation unless "plainly erroneous or inconsistent with the regulation") (quoting *Auer v. Robbins*, 519 U.S. 452, 461 (1997)). Given the abovementioned under-inclusion risk, which would frustrate the purpose of protecting the IND file's contents, it is reasonable to construe "other related submissions" to include internal agency emails as well—that is, provided they relate to the underlying application. *See* 21 C.F.R. § 601.51(a); 21 C.F.R. § 10.3(a). (*See* PRCS at 1, 4.) Indeed, the regulation appears to contemplate this arrangement. Subsection (e) lists the "data and information *in the biological product file*" that becomes publicly available after a licensing decision. § 601.51(e) (emphasis added).

The list includes, among other things, "[a]ll correspondence and written summaries of oral discussions relating to the biological product file." § 601.51(e)(6). Circularity aside, the agency reasonably interpreted the regulation to include application-related internal correspondence.

Each of the 60 documents here is either an internal FDA email or an email between the agency and an IND sponsor.[11] Plaintiff only disputes the former's inclusion.[12] (*See* Mem. at 9 (disputing inclusion of "all inter-agency and intra-agency government e-mails").) Plaintiff nevertheless omits any argument that they are not reasonably related to the ZMapp application. These internal emails include status updates regarding the expanded access submission, discussions about information to request from IND sponsors, the location of doctors familiar with ZMapp's administration, and discussions concerning sponsor-submitted information. Defendant maintains that each belongs in the IND file because it pertains to ZMapp, which has an active IND application. (*See* DMJS at 10–12.) The descriptions in the *Vaughn* index reasonably support this conclusion. And that is all the law requires.[13] *See Lewis*, 823 F.2d at 378 ("If the affidavits contain reasonably detailed descriptions of the documents and allege facts sufficient to establish an exemption, the district court need look no further.") (quotation omitted).

IT IS ORDERED denying Plaintiff's Third Motion for Summary Judgment (Doc. 73) and granting Defendant's Renewed Motion for Summary Judgment (Doc. 77).

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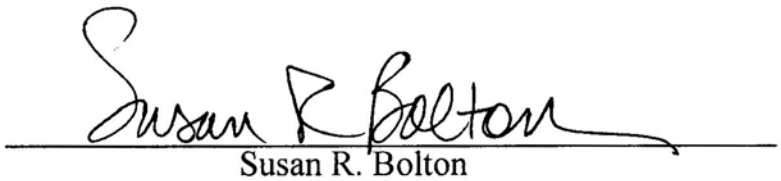
[11] (*See* RCVI lines 2–3, 7–8, 13, 16, 18–19, 22–23, 27–36, 38, 41, 43–44, 47–50, 56–58, 60, 72, 76, 79, 80–83, 85–86, 89, 91–98, 100–101, 103–105, 107, 109–111, 113.)

[12] Plaintiff does not appear to object to the latter group's placement in the IND file. Plaintiff instead argues that these records should be disclosed because Defendant continues to categorize them as nonresponsive without listing a separate exemption. (*See* PMSJ at 4–8.) That may be true; however, the *Vaughn* index did explain that these emails pertain to the ZMapp application, and as such, are part of the IND file. (*See also* DMSJ at 10.) Because all legitimate IND file contents are exempt, no further discussion is necessary. (*See* Jan. 24, 2018 Order at 5–6, 12.)

[13] Otherwise-segregable information in the IND file is also exempt. (*See* Jan. 24, 2018 Order at 12 (". . . Defendant need not explain the segregability of information contained in those documents rightfully housed in the IND file.").)

IT IS FURTHER ORDERED directing the Clerk to enter judgment in favor of Defendant and against Plaintiff.

Dated this 8th day of February, 2019.



Susan R. Bolton
United States District Judge