IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMA SYSTEMS, LLC, *et al.*,	*	
Plaintiffs,	*	
v.	*	**Civ. No. DLB-23-489**
U.S. FOOD & DRUG ADMINISTRATION, *et al.*,	*	
Defendants.	*	

MEMORANDUM OPINION

AMA Systems, LLC and Bluemar Promotions, LLC claim the U.S. Food and Drug Administration ("FDA") and Robert M. Califf, M.D., in his official capacity as FDA Commissioner, are withholding from them the file for an emergency use authorization request from Shenzhen Centurion Technology Co. LTD. ("SCT") in violation of the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. ECF 1. Pending before the Court are the defendants' motion for summary judgment, ECF 25, and the plaintiffs' Rule 56(d) request for discovery, ECF 26. The motion is fully briefed. ECF 25-1, 26, 27. No hearing is necessary. *See* Loc. R. 105.6. For the following reasons, the plaintiffs' request for discovery is denied and the defendants' motion for summary judgment is granted in part and denied in part.

I. Background

Federal law empowers the FDA to grant emergency use authorizations ("EUAs"), which permit the sale "of a drug, device, or product intended for use in an actual or potential emergency." 21 U.S.C. § 360bbb-3(a)(1). On February 4, 2020, the FDA Commissioner determined that COVID-19 constituted a "public health emergency." Emergency Use Authorization Declaration, 95 Fed. Reg. 18250, 18250 (Apr. 1, 2020). To mitigate the spread of the virus, the FDA announced

on August 5, 2020 that it would authorize "disposable, single-use surgical masks" for emergency use as personal protective equipment ("PPE"). ECF 25-1, at 7. A PPE manufacturer could obtain authorization pursuant to this EUA only by applying to the FDA. ECF 25-3, ¶ 10. The FDA recommended that any EUA request include:

> (1) a description of the product; (2) a description of the product's approval status; (3) the need for the product; (4) availability and effectiveness information for the product; (5) a discussion of risks and benefits of the product; (5) information on chemistry, manufacturing, and controls; a list site where the product is or would be manufactured, and the current good manufacturing practice status of the manufacturing site(s); (6) information about the quantity of the finished product on hand and the surge capabilities of the manufacturing site(s); (7) information comparable to an FDA-approved package insert or instructions for use; drafts of the "Fact Sheets" to be furnished to health care professionals or authorized dispenser and recipients of the product; and a discussion of the feasibility of providing such information in an emergency; (8) if seeking an extension of a product's labeled expiration date, any information in support of such an extension; and (9) any right of reference, as applicable.

Id. ¶ 11.

As a matter of policy and of the agency's interpretation of applicable law, the FDA would not publicly disclose the existence of an EUA request unless the requesting entity already had acknowledged the request in public. *Id.* ¶¶ 16–18, 33. Similarly, as a matter of policy and its interpretation of the law, the FDA would not publicly disclose the content of a pending EUA request. *Id.* ¶¶ 19, 37. As the FDA saw it—and still does—this information is exempt from FOIA disclosure under 5 U.S.C. § 552(b)(4) ("Exemption Four"), which protects "trade secrets and commercial or financial information obtained from a person and privileged or confidential." *Id.* ¶ 37.

At some point before February 17, 2021, SCT filed an EUA request for PPE it manufactured. ECF 25-3, ¶¶ 27, 29. The FDA did not authorize the request. *Id.* ¶ 31.

On February 17, 2021, the plaintiffs submitted a FOIA request to the FDA. ECF 25-2, ¶ 12. In their request, the plaintiffs sought:

> All Emergency Use Authorizations, including any form filed or any information, correspondence and/or documentation submitted with each Emergency Use Authorization for PPE for the following entities: 3B Tech, Inc.[;] Pro-Com Products, Inc.[;] Salusen, Inc.[;] Shenzhen Centurion Technology Co. LTD.[; and] J&F Technology Services LLC on behalf of Shenzhen Centurion Technology Co. LTD. Please include with the response any correspondence between the FDA and each entity and any marketing authorization letter or certificate provided to the FDA from any of the above referenced entities, including correspondence associated therewith.

Id.; *see also id.* at 8. That same day, the FDA acknowledged receipt. *Id.* ¶ 13. Shortly thereafter, the agency cautioned the plaintiffs that due to increased demand generated by the pandemic, FOIA "requests for medical device approval records" could take as long as 24 months. ECF 1, ¶ 10; ECF 19 ¶ 10.

About a week after the plaintiffs filed their request, Sarah Kotler, the Director of the Division of Freedom of Information ("DFOI") at the FDA, ECF 25-2, ¶ 1, emailed them to advise that they could find any approved EUA request on the FDA's website, *id.* ¶ 14. In response, the plaintiffs' counsel clarified that their client was seeking "applications, documents, materials, certifications, papers, communications etc. that were submitted by the [ ] companies with regarding to obtaining an EUA from the FDA for PPE." *Id.* ¶ 15. With that clarification in hand, DFOI assigned the request to the FDA's Center for Devices and Radiological Health ("CDRH"). *Id.* ¶ 16. At some point—it is unclear whether before or after this litigation began—CDRH staff determined that there were 43 pages of documents responsive to the plaintiffs' FOIA request, all of which pertained to an EUA request submitted by SCT ("the file"). ECF 25-3, ¶¶ 27, 29. These documents include information submitted to the FDA by SCT as well as communications between the agency and SCT. *Id.* ¶ 44.

On February 22, 2023—after waiting nearly two years and receiving no definitive response—the plaintiffs filed their complaint in this case, asserting that the FDA and Califf were withholding responsive documents in violation of FOIA. ECF 1.

On March 21, 2023, CDRH informed DFOI that the FDA had not authorized any EUA request from any of the entities the plaintiffs had named. ECF 25-2, ¶ 17. CDRH also notified DFOI that it found no evidence that any of those entities ever had publicly claimed that they submitted an EUA request to the FDA. *Id.* As a result, on March 22, DFOI informed the plaintiffs that the FDA had "completed processing" of their FOIA request and that "FDA can neither confirm nor deny the existence of records that would be responsive to your request, as doing so could reveal confidential commercial information." *Id.* at 8.

In response, the plaintiffs submitted to CDRH correspondence indicating that the entities the plaintiffs had named in their request had told the plaintiffs that they had submitted EUA requests. *Id.* ¶ 20. In light of that evidence, Candace Davis—the Division Director for the Division of Information Disclosure at CDRH—and her staff reviewed the file and determined that although its existence was no longer confidential commercial information, the content was exempt from FOIA disclosure under Exemption Four. ECF 25-3, ¶¶ 36–37.

On April 17, the FDA revised its response to the plaintiffs, informing them:

> After considering the documentation you provided us on April 4, 2023 and April 13, 2023, we are denying your request for records regarding Shenzhen Centurion Technology Co. LTD. We have no records responsive to your request for records regarding 3B Tech, Inc.; Pro-Com Products, Inc.; Salusen, Inc.; or J&F Technology Services LLC. We are denying the records regarding Shenzhen Centurion Technology Co. LTD. in accordance with the following FOIA (5 U.S.C. 552) Exemption(s): (b)(4).

ECF 25-2, at 11. The FDA did not prepare or provide a *Vaughn* index—that is, a list describing the documents the agency withheld, *Rein v. U.S. Patent & Trademark Off.*, 553 F.3d 353, 357 n.6

(4th Cir. 2009)—on the ground that "a *Vaughn* index would contain only one entry for the EUA request file (43 pages), which was withheld in full," ECF 25-3, ¶ 39. And the FDA did not provide the plaintiffs any non-exempt portions of the file that might be segregable from the exempt portions, on the ground that "there are no reasonably segregable portions of the file" and "there are no responsive documents that are not considered part of the file." *Id.*

On May 24, 2023, the defendants moved for summary judgment. ECF 25. The plaintiffs opposed the motion and requested discovery pursuant to Rule 56(d). ECF 26. The defendants replied. ECF 27. On January 29, 2024, the Court ordered the defendants to submit the file for *in camera* review. ECF 28. The defendants submitted the file on February 7. The Court has reviewed it.

II. Standard of Review

Summary judgment is appropriate when the movant "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). To meet its burden, the moving party must identify "particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials" in support of its position. Fed. R. Civ. P. 56(c)(1)(A). The relevant inquiry is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251–52 (1986).

The Court must "view the evidence in the light most favorable to the nonmoving party" and avoid "weigh[ing] the evidence or mak[ing] credibility determinations." *Lee v. Town of Seaboard*, 863 F.3d 323, 327 (4th Cir. 2017) (quoting *Jacobs v. N.C. Admin. Off. of the Courts*, 780 F.3d 562, 568–69 (4th Cir. 2015)) (internal quotation marks omitted). However, the Court

also must abide by its "affirmative obligation . . . to prevent factually unsupported claims and defenses from proceeding to trial." *Drewitt v. Pratt*, 999 F.2d 774, 778–79 (4th Cir. 1993) (quoting *Felty v. Graves-Humphreys Co.*, 818 F.2d 1126, 1128 (4th Cir. 1987)) (internal quotation marks omitted).

If the moving party demonstrates "an absence of evidence to support the nonmoving party's case," the burden shifts to the nonmoving party to "present specific facts showing that there is a genuine issue for trial." *Humphreys & Partners Architects, L.P. v. Lessard Design, Inc.*, 790 F.3d 532, 540 (4th Cir. 2015). A factual dispute is genuine only where there is sufficient evidence to permit a reasonable jury to find in the nonmoving party's favor. *Id.*; *see also Perkins v. Int'l Paper Co.*, 936 F.3d 196, 205 (4th Cir. 2019). "To create a genuine issue for trial, 'the nonmoving party must rely on more than conclusory allegations, mere speculation, the building of one inference upon another, or the mere existence of a scintilla of evidence.'" *Humphreys & Partners Architects*, 790 F.3d at 540 (quoting *Dash v. Mayweather*, 731 F.3d 303, 311 (4th Cir. 2013)).

In general, summary judgment should only be granted "after adequate time for discovery." *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Summary judgment before discovery can "force[] the non-moving party into a fencing match without a sword or mask." *McCray v. Maryland Dep't of Transp., Maryland Transit Admin.*, 741 F.3d 480, 483 (4th Cir. 2014). When the non-moving party has not had time for sufficient discovery, they may file a Rule 56(d) affidavit detailing the specific facts yet to be discovered that are necessary to defeat summary judgment. *Nader v. Blair*, 549 F.3d 953, 961 (4th Cir. 2008).

"The rule mandates that summary judgment be postponed when the nonmovant has not had the opportunity to discover information that is essential to his opposition." *Hodgin v. UTC Fire & Sec. Americas Corp.*, 885 F.3d 243, 250 (4th Cir. 2018) (cleaned up). "However, a court may

deny a Rule 56(d) motion for discovery when the information sought would not by itself create a genuine issue of material fact sufficient for the nonmovant to survive summary judgment." *Id.* (internal quotation marks omitted). To justify a denial of summary judgment on the grounds that additional discovery is necessary, the facts identified in a Rule 56 affidavit must be "essential to … [the] opposition." Fed. R. Civ. P. 56(d). A nonmoving party's Rule 56(d) request for additional discovery is properly denied "where the additional evidence sought for discovery would not have by itself created a genuine issue of material fact sufficient to defeat summary judgment." *Strag v. Bd. of Trs., Craven Cmty. Coll.*, 55 F.3d 943, 954 (4th Cir. 1995).

"FOIA cases are generally resolved on summary judgment once the documents have been properly identified." *Wickwire Gavin, P.C. v. U.S. Postal Serv.*, 356 F.3d 588, 591 (4th Cir. 2004).

> Summary judgment is warranted on the basis of agency affidavits when the affidavits describe 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.

Larson v. Dep't of State, 565 F.3d 857, 862 (D.C. Cir. 2009).

III. Discussion

"FOIA requires each governmental agency to provide information to the public on request." *Ethyl Corp. v. U.S. Env't Prot. Agency*, 25 F.3d 1241, 1245 (4th Cir. 1994). However, FOIA also exempts enumerated categories of information from disclosure. *See Wickwire Gavin*, 356 F.3d at 592 (citing 5 U.S.C. § 552(b)). "The burden of demonstrating that a requested document falls under an exemption rests on the government." *Hunton & Williams v. U.S. Dep't of Just.*, 590 F.3d 272, 276 (4th Cir. 2010).

The defendants have demonstrated that the file consists primarily of information exempt from disclosure under FOIA. As to that information, the defendants have met the additional

requirements of the FOIA Improvement Act ("FIA") as well. However, the Court finds that one communication in the file is not exempt and is reasonably segregable from the exempt material.

A. Discovery

As a threshold matter, the plaintiffs have not demonstrated that discovery is necessary before the Court rules on the motion for summary judgment.

In most contexts, Rule 56(d) motions are "broadly favored." *Greater Balt. Ctr. for Pregnancy Concerns, Inc. v. Mayor & City Council of Balt.*, 721 F.3d 264, 281 (4th Cir. 2013) (quoting *Raby v. Livingston*, 600 F.3d 552, 561 (5th Cir. 2010)). In FOIA cases, they are not. *Heily v. U.S. Dep't of Com.*, 69 Fed. App'x 171, 174 (4th Cir. 2003). "Discovery in FOIA cases is rare." *Goldner v. Soc. Sec. Admin.*, 293 F. Supp. 3d 540, 544 (D. Md. 2017) (cleaned up) (quoting *Schrecker v. U.S. Dep't of Just.*, 217 F. Supp. 2d 29, 35 (D.D.C. 2002)). "When the courts have permitted discovery in FOIA cases, it generally is limited to the scope of the agency's search and its indexing and classification procedures." *Heily*, 69 Fed. App'x at 174 (citing *Weisberg v. U.S. Dep't of Just.,* 627 F.2d 365, 371 (D.C. Cir. 1980)).

The plaintiffs' Rule 56(d) affidavit does not establish a need for discovery. The plaintiffs list six discrete facts they seek to discover. ECF 26-9, ¶¶ 3–8. None of them falls within the normal purview of FOIA discovery: "whether an agency has [] taken adequate steps to uncover responsive documents." *Schrecker*, 217 F. Supp. 2d at 35. What's more, the affidavit does not articulate any facts "essential to the opposition" such that summary judgment before discovery is inappropriate. Fed. R. Civ. P. 56(d).

First, the plaintiffs say that they "do not know what information is contained within the 43 pages of documents the FDA contends are responsive." ECF 26-9, ¶ 3. The plaintiffs know that the file contains SCT's request for an EUA for PPE, what information that sort of request generally

includes, and the fact that the FDA did not authorize the request. *See* ECF 25-2, at 11; ECF 25-3, ¶¶ 11, 27, 29, 31. Sharing anything more in advance of summary judgment risks revealing the information this dispute concerns. The plaintiffs' request

> for further inquiry into the substance of the documents would, if granted, turn FOIA on its head, awarding [them] in discovery the very remedy for which [they] seek[] to prevail in the suit. The courts must not grant FOIA plaintiffs discovery that would be tantamount to granting the final relief sought.

See Tax Analysts v. Internal Rev. Serv., 410 F.3d 715, 722 (D.C. Cir. 2005) (internal quotation omitted). Of course, if the agency had denied the plaintiffs information about what type of material the file contained—for instance, whether the responsive documents even included EUA request materials—the plaintiffs could have charged legitimately that they did not know enough to dispute the Exemption Four claim. But that is not the case. At this stage, the agency is only required to disclose "that which would have been provided in a full *Vaughn* Index of all of the documents." *Id.* at 720. The defendants attest that they have done so. ECF 25-3, ¶¶ 39–42. After reviewing the documents *in camera*, the Court agrees that they have.

The second, third, and fourth facts the plaintiffs seek concern the FDA's communication with SCT: whether the agency advised the company to mark its documents confidential commercial information and the company did so, ECF 28-9, ¶ 4; whether SCT remains in business and objected to the production of the file, *id.* ¶ 5; and whether the FDA attempted to contact SCT and obtain consent to produce the file, *id.* ¶ 6. The FDA has already informed the plaintiffs that it attempted to obtain SCT's consent to disclose the file. ECF 25, at 9 n.4. In any event, none of these facts is "essential" to the plaintiffs' opposition to summary judgment. Whether the file falls within the scope of Exemption Four does not depend on whether SCT marked the files confidential commercial information because an "implied assurance of confidentiality fairly can be inferred" from "generic circumstances." *See U.S. Dep't of Just. v. Landano*, 508 U.S. 165, 179 (1993); *see*

also Seife v. Food & Drug Admin., 492 F. Supp. 3d 269, 276 (S.D.N.Y. 2020), *aff'd*, 43 F.4th 231 (2d Cir. 2022). If the FDA's basis for withholding the file was that SCT marked its contents confidential, that SCT objected to disclosure, or that it could not obtain SCT's consent to release them, then these facts might matter. That is not the case.

Fifth, the plaintiffs seek to discover whether individuals affiliated with other companies submitted the documents in the file to the FDA on SCT's behalf. ECF 26-9, ¶ 7. The FDA already informed the plaintiffs that it did not have records for any EUA requests from the other companies the plaintiffs have named. ECF 25-3, ¶¶ 27–30. And whether SCT, or someone on their behalf, made SCT's submissions has no bearing on the question at hand: whether the FDA lawfully declined to disclose the file pursuant to Exemption Four.

Sixth and finally, the plaintiffs seek to "authenticate the FDA Registration Certificate or the Certificate of FDA Registration" that SCT or an affiliate provided the plaintiffs. ECF 26-9, ¶ 8. Whatever the plaintiffs might want this information for, the existence and authenticity of any such certificate is irrelevant to whether the FDA properly withheld the file. The plaintiffs do not attempt to show otherwise.

In briefing, the plaintiffs add that they hope to discover "(i) what records the FDA received from SCT; (ii) what records the FDA provided to SCT; (iii) what records the FDA is in possession of and is withholding; and (iv) why no redacted documents were produced, amongst other topics." ECF 26, at 12. The first three items simply reiterate their bid to learn the substance of the file. That request for discovery, as the Court has said already, "would, if granted, turn FOIA on its head." *See Tax Analysts*, 410 F.3d at 722. And the FDA already has provided two affidavits explaining in detail how it searched for and identified responsive documents and why it could not provide redacted copies without compromising confidentiality. ECF 25-2, ¶¶ 12–21; ECF 25-3,

¶¶ 20–42. What the plaintiffs seem to mean by their request about redaction is that the FDA could have provided redacted copies of the documents without revealing information protected by Exemption Four. But that is an argument about the merits, not an argument that discovery is essential to demonstrating the existence of a genuine dispute of material fact.

The plaintiffs have not established that discovery is essential to their opposition to the motion for summary judgment. And none of the information they request is within the scope of ordinary FOIA discovery. In consequence, the Court denies the plaintiffs' request for discovery.

B. Exemption Four

Proceeding to the merits of the defendant's motion for summary judgment, the Court finds that the file contains information exempt from disclosure under FOIA Exemption Four. That exemption covers "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). "To establish that Exemption 4 applies, the government must therefore show that the documents at issue are (1) trade secrets or commercial or financial information, (2) that were obtained from a person outside the government, and (3) are privileged or confidential." *Am. Mgmt. Servs., LLC v. Dep't of the Army*, 703 F.3d 724, 729 (4th Cir. 2013). There is no dispute that the file includes information the FDA obtained from SCT, "a person outside the government." Nor is there any genuine dispute that the information is commercial or financial—it concerns a medical device SCT manufactured for sale. *See Citizens for Resp. & Ethics in Wash. v. U.S. Dep't of Just.*, 58 F.4th 1255, 1265 (D.C. Cir. 2023) ("[H]ealth and safety data that medical device manufacturers submit[] to the Food and Drug Administration [is] commercial information.") (citing *Pub. Citizen Health Rsch. Grp. v. FDA*, 704 F.2d 1280, 1290 (D.C. Cir. 1983)). With the exception of the communication the Court discusses in Part III.D, the sole genuinely contested issue is whether the information is confidential.

Determining whether the information is confidential is complicated by the Supreme Court's relatively recent ruling in *Food Marketing Institute v. Argus Leader Media*, 139 S. Ct. 2356 (2019). Before that decision, the Fourth Circuit used the "*National Parks* Test," under which "[i]nformation is confidential if its disclosure is likely to (1) impair the Government's ability to obtain necessary information in the future, or (2) cause substantial harm to the competitive position of the person from whom the information was obtained." *Am. Mgmt. Servs.*, 703 F.3d at 730 (cleaned up) (quoting *Acumenics Rsch. & Tech. v. U.S. Dep't of Just.*, 843 F.2d 800, 807 (4th Cir. 1988)). In *Argus Leader*, the Supreme Court repudiated the *National Parks* Test. 139 S. Ct. at 2366. Now, "[a]t least where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is 'confidential' within the meaning of Exemption 4."[1] *Id.* Because the new test is so different from the old test and the Fourth Circuit has not yet applied *Argus Leader*, there is no binding precedent on point—particularly on which information is "customarily" treated as private. Indeed, because few federal courts in any jurisdiction have applied *Argus Leader* to that issue, there is not much persuasive authority either. *But see, e.g.*, *Flyers Rights Educ. Fund, Inc. v. Fed. Aviation Admin.*, 71 F.4th 1051, 1055 (D.C. Cir. 2023) (applying *Argus Leader* standard to determine whether information is customarily treated as private). Between them, the parties cite only two rulings in a single case applying the *Argus Leader* definition of confidentiality: *Seife v. Food & Drug Admin.*, 492 F. Supp. 3d 269 (S.D.N.Y. 2020), *aff'd*, 43 F.4th 231 (2d Cir. 2022).

[1] The Supreme Court did not decide whether the second condition—provision to the government under an assurance of privacy—is necessary. *See Food Marketing Institute v. Argus Leader Media*, 139 S. Ct. 2356, 2363 (2019). This Court will assume that it is; if it is not, then the analysis of the first condition suffices.

When it comes to identifying what counts as information that is "customarily . . . treated as private," *Argus Leader*, 139 S. Ct. at 2366, there is not much available.

But there is a workaround. For decades before *Argus Leader*, the U.S. Court of Appeals for the District of Columbia Circuit used a similar test for information voluntarily submitted to the government: Under that test, information is "confidential" under Exemption Four if, but only if, "it is of a kind that the provider would not customarily make available to the public." *Critical Mass Energy Project v. Nuclear Regul. Comm'n*, 975 F.2d 871, 872 (D.C. Cir. 1992) (en banc); *see also Argus Leader*, 139 S. Ct. at 2365 (quoting the *Critical Mass* Test with approval). The Fourth Circuit did not adopt the *Critical Mass* Test. *See Am. Mgmt. Servs.*, 703 F.3d at 731 n.6. However, the Fourth Circuit determined that if a document were confidential under *National Parks*, it would be confidential under *Critical Mass*:

> Confidentiality under the *Critical Mass* Test is broader than confidentiality under the *National Parks* Test . . . . In other words, if public disclosure of a document is likely to impair the government's ability to obtain necessary information in the future or cause substantial harm to a company's competitive position, that document will most certainly also contain information that the provider would not customarily make available to the public.

Id. There are two upshots. If the information in the file would be confidential under *Critical Mass*, then it would "customarily . . . be treated as private" under *Argus Leader*. *See* 139 S. Ct. at 2366. The same is true if the information would be confidential under *National Parks* because *Critical Mass* encompassed everything *National Parks* did and more—at least according to the Fourth Circuit. As a result, cases applying *Critical Mass* and *National Parks* may serve as persuasive authority for the determination of whether information would "customarily . . . be treated as private" under *Argus Leader*. *See* 139 S. Ct. at 2366.

The vast majority of the information in the file is confidential under *Argus Leader*. First, the record indicates that SCT actually and customarily treated the information as private. The

defendants aver that to their knowledge, SCT has never made the content of the file public. ECF 25-3, ¶ 40. When the defendants searched the internet for any public acknowledgment by SCT of its EUA request, they found none. *Id.* ¶ 32. While the plaintiffs ultimately produced correspondence showing that SCT acknowledged the *existence* of that request to them, they did not produce any documents showing that SCT shared any of the *content* of the request. *See id.* ¶¶ 34–36; ECF 26-8, at 2. This type of evidence can establish how a provider of information treats the information for purposes of Exemption Four. *See Ctr. for Med. Progress v. U.S. Dep't of Health & Human Servs.*, No. 21-642 (BAH), 2022 WL 4016617, at *10 (D.D.C. Sept. 3, 2022). The plaintiffs produce nothing to suggest otherwise. The result would be no different even if SCT "publicly shared the information at issue when it collaborated with third parties" like those the plaintiffs name, as long as SCT did not also share it with the general public. *See Seife*, 492 F.3d at 276 (citing *Parker v. Bureau of Land Mgmt.*, 141 F. Supp. 2d 71, 79 (D.D.C. 2001)).

The case law confirms that the information in the file is the sort that is customarily treated as private. Consider the only post-*Argus Leader* decisions the parties cite on this issue: the district court and court of appeals decisions in *Seife v. Food & Drug Administration*. 492 F. Supp. 3d 269 (S.D.N.Y. 2020), *aff'd*, 43 F.4th 231 (2d Cir. 2022). In *Seife*, the plaintiff brought a FOIA case against the FDA to obtain copies of the materials a drug company submitted to secure the agency's approval of a drug. 492 F. Supp. 3d at 271–73. After consultation with the FDA, the company consented to FDA disclosure of a version of the materials redacted to exclude information protected by Exemption Four. *Id.* at 273. On cross-motions for summary judgment, the plaintiff challenged many of the redactions as protecting information outside the exemption's scope. *Id.* The district court granted summary judgment for the FDA, *id.* at 281, finding that the withheld information—clinical studies and drug efficacy data—was actually and customarily kept private,

id. at 275–76. When the plaintiff appealed, the Second Circuit affirmed, briskly concluding that the information the plaintiff sought "falls squarely within Exemption 4" before focusing its discussion on other issues. *Seife*, 43 F.4th at 238 n.6. A recent D.C. Circuit case, *Flyers Rights*, further supports the notion that information submitted to the government to secure regulatory approval of a product is typically confidential. *See* 71 F.4th 1051 (D.C. Cir. 2023). There the D.C. Circuit, applying *Argus Leader*, found that the information Boeing submitted to the Federal Aviation Administration in its application to recertify the Boeing 737 MAX for service—primarily, information about redesigned hardware and software—was the sort of information actually and customarily kept private. *See id.* at 1054–55.

Courts applying the *National Parks* Test in the years before *Argus Leader* recognized that applications for FDA approval of medical devices contained confidential information as well. *See, e.g.*, *Henson v. Dep't of Health & Human Servs.*, 892 F.3d 868, 877 (7th Cir. 2018) (finding submission about materials used to manufacture a medical device were confidential); *Heeney v. Food & Drug Admin.*, No. CV 97–5461 MMM (CTx), 1999 WL 35136489, at *7–9 (C.D. Cal. Mar. 16, 1999) (finding submission about materials used to manufacture a medical device, "[d]esign and testing data" about the device, and the identity of the manufacturer of one of the device's parts were confidential). Because documents that satisfy the *National Parks* Test "most certainly also contain information that the provider would not customarily make available to the public," *Am. Mgmt. Servs.*, 703 F.3d at 731 n.6, the fact that the file would be confidential under that now-defunct test implies that it contains the sort of information that would count as private under the *Argus Leader* Test.

Second, SCT submitted its request for an EUA to the FDA under an implied assurance of privacy created by FDA practice and regulations. *See U.S. Dep't of Just. v. Landano*, 508 U.S.

165, 179 (1993); *Seife*, 492 F. Supp. 3d at 276. "FDA does not make public any information about pending or unauthorized EUA requests for PPE." ECF 25-3, ¶ 4. The agency does not disclose EUA request files "unless the sponsor expressly waives the confidentiality" of the material. *Id.* ¶ 19. Indeed, the FDA does not disclose even the existence of pending EUA requests unless the sponsor has already done so. *Id.* ¶¶ 17–18. These practices implicitly assure applicants that the FDA will not disclose their information while their applications are pending.

FDA regulations bolster that assurance. 21 C.F.R. § 20.61 provides that "[d]ata and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure." 21 C.F.R. § 20.61(c). The FDA interprets 21 C.F.R. § 20.61 to cover the existence and content of a pending EUA request that has not been publicly disclosed by the sponsor. ECF 25-3, ¶¶ 16, 18–19. FDA regulations also prohibit the disclosure of comparable material about medical devices submitted through other approval processes. *Id.* ¶ 16 (citing 21 C.F.R §§ 807.95, 812.38, 814.9). Together, these regulations and FDA practice give rise to an implied assurance of confidentiality. *See Seife*, 43 F.4th 231 at 238 n.6; *Seife*, 492 F. Supp. 3d at 276 ("The nature of the pharmaceutical industry and the FDA regulations themselves support this inference.").

The conclusion is simple. The file consists primarily of information customarily and actually kept private by SCT. SCT submitted the information under an implied assurance of privacy. As a result, the vast majority of the file is exempt from disclosure under Exemption Four.

The plaintiffs make two counterarguments. First, they contend that because SCT's masks were publicly available at the time of their FOIA request, the information in SCT's application for an EUA is not confidential. Even assuming that the EUA at issue is in fact an EUA for the masks

SCT already sold in the United States, this argument falls short. The plaintiffs cite no authority for the legal premise of their argument. Nor could they. Courts have consistently rejected the argument that the fact that a device is available to the public means the information contained in the application for regulatory authorization of the device is not confidential. *See, e.g.*, *Henson*, 892 F.3d at 872, 877 (affirming district court finding that redacted contents of premarket approval application for publicly available glucose monitoring system fell within Exemption Four); *Heeney*, 1999 WL 35136489, at *7–9 (finding FDA properly withheld contents of application for approval of publicly available electrode catheter pursuant to Exemption Four). There is good reason for that. "If market presence alone were all that was required to trigger disclosure under FOIA, manufacturers would be loathe to provide data relevant to consideration of their [authorization] request[s], and the FDA's ability to carry out its regulatory objectives would be thwarted." *Heeney*, 1999 WL 35136489, at *9. The availability of SCT masks does not take the content of SCT's EUA application outside the scope of Exemption Four.

Second, the plaintiffs argue that the file does not contain confidential information because the FDA is authorized by statute to publish summaries of EUA applications that have been authorized, terminated, or revoked. *See* 21 U.S.C. § 360bbb-3(h)(1). However, SCT's application has not been authorized, terminated, or revoked, so that provision does not apply. Even if it did, the fact that this statute *permits* the FDA to provide the public a *summary* of an application like this one does not entail that the FDA has an *obligation* to provide the public the *application itself*. Nor does it entail that the information is not confidential under FOIA. If anything, the fact that § 360bbb-3(h)(1) authorizes the FDA to disclose summaries of EUA applications that have been authorized, terminated, or revoked implies that by default, the FDA may not disclose the underlying materials or summaries of pending applications. *Cf. Elec. Priv. Info. Ctr. v. Internal*

Rev. Serv., 910 F.3d 1232, 1243 (D.C. Cir. 2018) (reasoning that because "the mention of one thing implies the exclusion of another thing," a statute authorizing the disclosure of a tax return in some circumstances implicitly bars disclosure under any others—including FOIA). Reinforcing that reading, § 360bbb-3(h)(1) is immediately followed by a subsection that stipulates that § 360bbb-3(h)(1) does not alter or amend Exemption Four, but rather constitutes a limited "disclosure authorized by law." *See* 21 U.S.C. § 360bbb-3(h)(2). This counterargument fails.

With the single exception the Court addresses below, the contents of the file are protected from disclosure by Exemption Four.

C. FOIA Improvement Act

The FIA authorizes the FDA to withhold the file as well. "[U]nder the FOIA Improvement Act of 2016, an agency may only withhold information under a FOIA exemption if it 'reasonably foresees that disclosure would harm an interest protected by an exemption[,]' or if 'disclosure is prohibited by law[.]'" *Campaign Legal Ctr. v. U.S. Dep't of Just.*, 34 F.4th 14, 19 (D.C. Cir. 2022) (alterations in original) (quoting 5 U.S.C. § 552(a)(8)(A)(i)).

With the exception addressed in the next section, the disclosure of the file is prohibited by law. The Trade Secrets Act provides that government employees may not disclose "information [that] concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association." 18 U.S.C. § 1905. The Fourth Circuit has held that "the scope of the Trade Secrets Act is co-extensive with that of exemption (4) of the FOIA." *Acumenics*, 843 F.2d at 806. "Thus, for information falling within exemption (4), the Trade Secrets Act does bar an agency decision to release the information." *Id.* at 806–07. Other circuits concur. *See, e.g.*, *Canadian Com. Corp. v. Dep't of Air Force*, 442 F.

Supp. 2d 15, 39 (D.D.C. 2006) ("[W]henever a party succeeds in demonstrating that its materials fall within Exemption 4, the government is precluded from releasing the information by virtue of the Trade Secrets Act.") (citing *McDonnell Douglas Corp. v. Widnall,* 57 F.3d 1162, 1164 (D.C. Cir. 1995)); *Synopsys, Inc. v. U.S. Dep't of Labor*, No. 20-16414 & 20-16416, 2022 WL 1501094, at *4 (9th Cir. May 12, 2022) ("[W]e and our sister circuits have long held that 'the scope of section 1905 and exemption (4) of the FOIA are the same or coextensive.'") (quoting *Pac. Architects & Eng'rs Inc. v. U.S. Dep't of State*, 906 F.2d 1345, 1347 (9th Cir. 1990)).

Because Exemption 4 covers the file (with the exception below), the Trade Secrets Act precludes the disclosure of the file. And because the Trade Secrets Act bars federal employees from disclosing the file, the FIA authorizes the defendants to withhold it from the plaintiffs.

D. Segregability

With one exception, any non-exempt information the file may contain is not reasonably segregable from the information protected by Exemption Four. "If an exemption applies only to a portion of a document, FOIA requires that '[a]ny reasonably segregable portion of a record shall be provided . . . after deletion of the portions which are exempt.'" *Solers, Inc. v. Internal Rev. Serv.*, 827 F.3d 323, 328 (4th Cir. 2016) (alterations in original) (quoting 5 U.S.C. § 552(b)). "When an agency demonstrates that records contain exempt information . . . it is entitled to a presumption that [it] complied with the obligation to disclose reasonably segregable material." *Flyers Rights Educ. Fund, Inc. v. Fed. Aviation Admin.*, 71 F.4th 1051, 1057–58 (D.C. Cir. 2023) (internal quotation omitted); *see also O'Neill v. U.S. Dep't of Just., Crim. Div.*, No. 2:18-cv-01517-DCN, 2020 WL 13065452, at *11 (D.S.C. Aug. 19, 2020).

The defendants maintain that the entire file is exempt from disclosure and that no portion of the file is reasonably segregable from exempt information. However, the only proof they submit

in support of their segregability claim is the arguably conclusory statement in the Davis affidavit that "there are no reasonably segregable portions of the file." ECF 25-3, ¶ 39. To determine whether the exempt information is reasonably segregable from any non-exempt information, the Court requested the file and reviewed it *in camera*. After diligent, line-by-line review, the Court finds that with one exception, any non-exempt information in the file is so "inextricably intertwined" with exempt information that the defendants could not reasonably segregate it. *See Rein*, 553 F.3d at 374 (quoting *Mead Data Cent., Inc. v. U.S. Dep't of Air Force*, 566 F.2d 242, 260 (D.C. Cir. 1977)); *Brown v. U.S. Dep't of Just.*, 734 F. Supp. 2d 99, 110–11 (D.D.C. 2010). In consequence, the Court grants the defendants' motion for summary judgment as to this portion of the file.

The exception is a single communication from the FDA to SCT. Exemption Four protects information from disclosure only if it was "obtained from a person outside the government." *Am. Mgmt. Servs.*, 703 F.3d at 729. In general, "[i]nformation generated within the Government is not obtained from a person and, thus, does not fall under the exemption." *Ctr. for Auto Safety v. U.S. Dep't of Treas.*, 133 F. Supp. 3d 109, 119 (D.D.C. 2015) (quotations omitted). The defendants acknowledge that the file contains "FDA's communications with Shenzhen Centurion about the EUA request." ECF 25-3, ¶ 44. The Court's review confirms that the file contains three copies of one communication from the FDA to SCT. Because that communication was "generated within the Government," rather than "obtained from a person outside the government," Exemption Four does not exempt that communication as a whole from disclosure. *See Ctr. for Auto Safety*, 133 F. Supp. 3d at 119, 123–27 (evaluating whether Exemption Four protects emails between the government and people outside the government based on who authored each email).

In briefing, the defendants insist that all of the information in the file, including any communications with SCT, is confidential. ECF 27, at 5. But the defendants offer no account of how this communication from agency officials constitutes information "obtained from a person outside the government"—a necessary condition for Exemption Four coverage. To be sure, a document the government produces may nevertheless count as information "obtained from a person" if the document essentially reproduces information that "was supplied to the agency by a person or could allow others to extrapolate such information." *Ctr. for Auto Safety*, 133 F. Supp. 3d at 123 (quoting *S. All. for Clean Energy v. U.S. Dep't of Energy*, 853 F. Supp. 2d 60, 68 (D.D.C. 2012)) (internal quotation marks omitted). But "the key distinction . . . is between information that is either repeated verbatim or slightly modified by the agency," which constitutes information obtained from outside the government, "and information that is substantially reformulated by the agency," which does not. *S. All. for Clean Energy*, 853 F. Supp. 2d at 68. Even if this communication from the FDA to SCT reflects information obtained from outside the government, the document as a whole falls squarely in the latter category. So Exemption Four does not protect this communication from disclosure.

This non-exempt communication can reasonably be segregated from the rest of the file. In some, if not all, of its three appearances, this communication is a discrete document or can be treated as one by severing it from others in the associated chain of communications. Segregating this communication from the rest of the file would be simple.

That leaves a final question: whether any discrete information within this communication is protected by Exemption Four and eligible for redaction. Lacking any guidance from the parties, the Court declines to answer this question in the first instance. By March 8, 2024, the defendants must take one of two actions: (i) disclose to the plaintiffs the communication in its entirety and

advise the Court the communication has been disclosed; or (ii) submit to the Court for *in camera* review a proposed redacted version of the communication and file on the docket a declaration from an FDA employee explaining why the redacted information is being withheld. If the defendants opt for (ii), either party may move for summary judgment upon the filing of the declaration.

IV. Conclusion

For the reasons above, the defendants' motion for summary judgment, ECF 25, is granted in part and denied in part: granted as to all of the file except the three copies of the communication from the FDA to SCT and denied without prejudice as to that communication. The plaintiffs' Rule 56(d) request for discovery, ECF 26, is denied. A separate order follows.

Date: February 21, 2024

Deborah L. Boardman
United States District Judge