UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

INFORMED CONSENT ACTION NETWORK, Plaintiff, v. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Civil Action No. 25-0825 (RDM)

DEFENDANTS' RESPONSE BRIEF

Pursuant to the Court's November 24, 2025 Order, Defendants Food and Drug Administration ("FDA") and the Department of Health and Human Services ("Department" or "HHS") (collectively "Defendants") respectfully submit this brief to provide FDA's position on whether the eighteen month stay should be granted, to update the Court on the agency's hiring and other efforts to reduce its FOIA backlog, and to respond to Plaintiff's Supplemental Brief regarding Defendants' "First In, First Out" Policy and Practice ("Pl. Supp. Brief"), ECF No. 22.

A stay should be granted for at least eighteen months until June 25, 2027. On June 13, 2025, FDA and HHS moved a stay under 5 U.S.C. § 552(a)(6)(C) and *Landis v. North American Co.*, 299 U.S. 248, 254 (1936), because of the unprecedented burdens from court orders in *Public Health & Medical Professionals for Transparency v. Food and Drug Administration*, Civ. A. No. 21-1058 (N.D. Tex.) ("*PHMPT I*"), and *Public Health & Medical Professionals for Transparency v. FDA*, Civ. A. No. 22-0915 (N.D. Tex.) ("*PHMPT II*"). *See* Defendants' Motion to Stay., ECF No. 14. The plaintiffs in *PHMPT I* and *PHMPT II* collectively sought approximately 5.7 million pages of records related to COVID-19 vaccines. On November 24, 2025, before ruling on Defendants' motion, the Court held a hearing and then permitted Plaintiff

to submit supplemental briefing "presenting evidence on the 'first-in-first-out' queuing system." *See* November 24, 2025, Minute Order. The Court also ordered FDA to submit a brief responding to Plaintiff's submission and addressing certain questions raised by the Court and denied FDA's motion to stay, without prejudice, but noted that it would treat Defendants' present response brief as a renewed motion. *Id.* Defendants now report, as set forth in the attached supplemental declaration of Suzann Burk ("Supp. Burk Decl.") (Ex. A hereto), that the disclosure office within FDA's Center for Biologics Evaluation and Research ("CBER" or "the Center") that is responsible for responding to the FOIA request at issue[1] continues to face exceptional circumstances due to the ongoing effects of the *PHMPT I* and *PHMPT II* orders and continues to exercise due diligence in meeting its obligations under FOIA.

FDA submits that this action should be stayed based on the developments in those cases previously reported, *i.e.*, court orders in *PHMPT I* and *PHMPT II* requiring FDA to produce an additional 3.4 million pages of records. As reported in Defendants' June 13, 2025, motion, *see* ECF No. 14, in *PHMPT I*, FDA was required to provide an additional production of approximately 600,000 pages by the court's June 30, 2025, deadline, *see* Mem. Op. & Order, *PHMPT I*, ECF No. 101 (Dec. 6, 2024). Because of stays entered in other cases, *see* Supp. Burk Decl. ¶ 38, FDA was able to complete its production in that case, *see* Supp. Burk Decl. ¶ 9. In *PHMPT II*, FDA must continue to dedicate its limited resources to producing an additional 2.8 million pages by the *PHMPT II* court's October 1, 2026, deadline. *See* Am. Order, *PHMPT II*, ECF No. 52 (June 9, 2025) (entering parties' negotiated schedule); Supp. Burk Decl. ¶ 10.

[1] For ease of reference, "CBER's disclosure staff" or "CBER's disclosure office" as used herein refers to the Division of Disclosure and Oversight Management, the Access Litigation and Freedom of Information Branch, and Special Disclosure Units within CBER's FOIA office. *See* Supp. Burk Decl. ¶¶ 1-4.

As described below, exceptional circumstances continue to exist, and FDA continues to exercise due diligence, which justify a stay. Defendants thus request that the Court issue a stay for at least an additional eighteen months, until June 25, 2027, after which time FDA anticipates being better situated to update the Court on its ability to process Plaintiff's FOIA Request No. 2024-965. Plaintiff's FOIA Request No. 2024-965 is currently positioned 471 in CBER's Complex Track, behind 470 other FOIA requests, including hundreds of Plaintiff's other requests (13 of which are also in litigation). Supp. Burk Decl. ¶ 39. At this time, FDA cannot reasonably estimate when Request No. 2024-965 will reach the top of the Complex Track; however, FDA anticipates that by June 25, 2027, it will have completed its processing obligations in *PHMPT II*, further processed its backlog of non-*PHMPT* related FOIA requests, and will be in a better position to evaluate when it might be able to respond to Plaintiff's FOIA request. *Id.* ¶ 41. If the requested stay is granted, Defendants propose filing a status report within two weeks after the end of the stay outlining their proposal for further proceedings in this case.

1. Exceptional Circumstances

Exceptional circumstances continue to exist. CBER has faced and is facing the immense burden, reported in Defendants' prior stay motion briefing, of the two orders in *PHMPT I* and *PHMPT II* requiring additional productions, increasing CBER's total production burden to more than 9 million pages of COVID-19 vaccine records by October 1, 2026. *See* Mem. Op. & Order, *PHMPT I*, ECF No. 101 (Dec. 6, 2024); Am. Order, *PHMPT II*, ECF No. 52 (June 9, 2025). In *PHMPT II*, FDA was previously ordered to produce a minimum of 180,000 pages per month starting in December 2023. *See* Supp. Burk Decl. ¶ 33.B. However, the true workload was greater; in actuality, FDA has had to produce on average more than 230,000 pages per month to ensure that production of responsive records was completed by the *PHMPT* court's June 2025 deadline.

Id. The *PHMPT* court thereafter added to that burden. On December 6, 2024, the court in *PHMPT I* ordered FDA to produce an additional set of records (an emergency use authorization file) consisting of approximately 600,000 additional pages by the same production deadline ordered in *PHMPT II*, June 30, 2025. *See* Mem. Op. & Order, *PHMPT I*, ECF No. 101 (Dec. 6, 2024). FDA completed production of approximately 600,000 additional pages of records by the court's June 30, 2025, deadline, and a small handful thereafter. Supp. Burk Decl. ¶ 9.

Pursuant to a follow-on order in *PHMPT II*, FDA must also produce two additional emergency use authorization files containing approximately 2.8 million pages in *PHMPT II*, for a total increase across both cases of 3.4 million pages. *See* Mem. Op. & Order, *PHMPT I*, ECF No. 101 (Dec. 6, 2024); Am. Order, *PHMPT II*, ECF No. 52 (June 9, 2025). These orders raise the number of pages collectively sought from approximately 5.7 million pages of records to 9.1 million pages, an increase of approximately 60 percent. Supp. Burk Decl. ¶ 10.

In *PHMPT II*, the court modified the production schedule and ordered FDA to produce the additional 2.8 million pages of records at the previous court-ordered rate of 180,000 pages per month. *See* Am. Order, *PHMPT II*, ECF No. 52 (June 9, 2025) (entering parties' negotiated schedule). Production of the additional records in *PHMPT II* must be completed by October 1, 2026. *See id.* (stating FDA will complete production of the Moderna emergency use authorization file by October 1, 2026). CBER's disclosure office continues to allocate its limited resources to comply with the *PHMPT* court's latest two orders extending the burden by millions of pages over the next 8 months. *See* Supp. Burk Decl. ¶ 11. Simply put, the burden that has been placed on the FDA is extreme, and clearly demonstrates the existence of exceptional circumstances.

2. FDA's Due Diligence

a. Hiring and Training Efforts

FDA continues to exercise due diligence. To comply with the *PHMPT I* and *PHMPT II* orders and fulfill its other responsibilities stemming from increased FOIA requests and litigation, the Center's disclosure office undertook aggressive efforts to hire additional staff and contractors, seek funding, and restructure its resources. *See* Supp. Burk Decl. ¶ 32. After the initial *PHMPT I* production order, CBER's disclosure office made large-scale changes to its staff and work processes. *Id.* After the initial *PHMPT II* production order, CBER's disclosure office significantly increased the number of contractors and brought on board six full-time employees between June and December 2023. *Id.* ¶ 34. In 2024, CBER's disclosure office hired eight more full-time employees. *Id.* On December 31, 2024, CBER's disclosure office had fourteen staff and eight contractors working primarily on *PHMPT I* and *PHMPT II* production orders, and eight staff assigned to review all other FOIA requests. *Id.* However, it takes approximately two years for new employees to be adequately trained as members of CBER's disclosure staff and to independently contribute to all of CBER's FOIA disclosure work (*i.e.*, staff are not generally assigned to work exclusively on one track). *Id.* ¶ 36. The training process initially slows the pace of processing outstanding requests because more senior employees must review the new employees' work carefully to ensure that records are being correctly reviewed for necessary redactions, including information that is confidential to third parties. *Id.* ¶¶ 14-16, 36. Thus, despite best efforts and the good-faith investment in increasing its future processing capacity by training new employees, CBER's disclosure office resources necessarily have been limited during this lengthy onboarding period. *Id.*

Additionally, a hiring freeze went into effect in January 2025. And throughout most of 2025, FDA faced unanticipated staff disruptions; several CBER disclosure staff members and contractors (primarily assisting with *PHMPT II*) departed the agency, including two senior staff members. Supp. Burk Decl. ¶ 35. By November 30, 2025, CBER's disclosure office had just nine staff and 6 contractors remaining to work on *PHMPT II*. *Id.* Eight staff assigned to review all other FOIA requests also remained, though their work was slowed by the staff disruptions, government shutdown, and administrative changes within the agency. *Id.* As a result of the hiring freeze and staff departures, nearly half of remaining staff are still within the two-year training period. *Id.* ¶ 35. Thus, while the factors discussed operated in tandem to further constrain the Center's resources, CBER's disclosure office continued to the best of its ability to comply with its production obligations in *PHMPT II* and process other FOIA requests. *See id.* ¶¶ 41, 43.

Lastly, FOIA is an unfunded mandate—that is, it is not a separate "line item" —category in legislative appropriations for the agency and, thus, FOIA operations must be funded from general budgetary appropriations. Declaration of Meredith Schlaifer ("Schlaifer Decl."), ECF No. 17-1, ¶ 14. FDA has not made a request for supplemental funding given its current limited budget and lower appropriations for FY26 than FY25. More recently, however, the agency has been engaged in an effort to onboard contractors for all centers, including CBER, with funding from a FY24 surplus. As of the date of this filing, FDA has onboarded 42 contractors, is in the process of onboarding two additional contractors, and has one vacancy in the process of being filled for FOIA work agency-wide. Eight of these contractors were allocated to CBER, which has already onboarded seven in recent weeks and is in the process of onboarding the eighth. Supp. Burk Decl. ¶ 35. These contractors, along with eight other full-time staff, will assist CBER with processing FOIA requests unrelated to *PHMPT II*, including, as their training permits, processing

requests in CBER's Complex Track. *Id.* Additionally, the agency was recently granted an exemption to the hiring freeze, and FDA's request to hire was granted for 60 positions for agency-wide FOIA work. FDA is awaiting clarity on its current budget allocation before commencing with additional hiring.

b. CBER's Processing Efforts

FDA's extraordinary efforts to comply with the court-ordered productions in *PHMPT I* and *II* while continuing work on other FOIA requests[2] far exceed what is necessary to show due diligence. Plaintiff now attempts to undermine this fact by arguing that FDA's public FOIA data shows a repeat pattern of out-of-order processing by the agency. Pl. Supp. Br. at 9-12. In doing so, Plaintiff asks this Court to invalidate longstanding FOIA processes that Congress has found adequate to show due diligence. Plaintiff's argument is further predicated on a false premise: that this Court must evaluate FDA's due diligence based on agency-wide processing of FOIA requests, and not just CBER's. But the Court need not and should not do so.

Nothing in the FOIA or its amendments prohibits a federal agency from implementing multi-track processing or other procedures, including decentralized processing, to manage and reduce its FOIA backlog. Def.'s Reply to Opp. to Motion to Stay, ECF No. 17, at 5-6; 5 U.S.C. § 552(a)(6)(D); Schlaifer Decl. ¶ 8. In fact, most large federal agencies employ decentralized processing systems based on the amount of time and/or work involved in responding to certain requests. *See e.g.*, 6 C.F.R. § 5.1(c) (Department of Homeland Security), 28 C.F.R. § 16.1(c) (Department of Justice) and 45 C.F.R. § 5.3 *FOIA Officer* (Department of Health and Human

[2] For example, at least two of Plaintiff's FOIA requests that are subject to litigation have reached the top of CBER's Complex Track, and CBER's disclosure office completed its production of responsive records to both requests. *See* Supp. Burk Decl. ¶ 25 (citing *Informed Consent Action Network v. FDA*, Civ. A. No. 25-2456 (TSC) (D.D.C.); *Informed Consent Action Network v. FDA*, Civ. A. No. 25-2457 (JEB) (D.D.C.)).

Services). In the present case, and numerous others brought by this Plaintiff, FDA has consistently explained that the agency has traditionally employed a decentralized process due to the highly technical and scientific nature of the records created by agency center components (*e.g.*, CBER) and the large number of records generated by each component. *See* Schlaifer Decl. ¶¶ 8 and 17; Supp. Burk Decl. ¶ 17. While each disclosure office is familiar with FOIA requirements and FDA's general disclosure regulations (21 C.F.R. Part 20), most FDA components have their own disclosure regulations (e.g., 21 C.F.R. Part 650) and staff are trained to review information regularly maintained by that center component. Schlaifer Decl. ¶ 17; *see* Supp. Burk Decl. ¶ 2 (describing CBER's role within FDA). Thus, any request received by the agency is assigned to the FDA component that is reasonably likely to possess responsive records, and, most importantly, the subject-matter expertise to conduct a search and determine whether the responsive records should be released in full, redacted in part, or withheld under FOIA.[3] Schlaifer Decl. ¶ 8. Courts have long found such decentralized systems to be reasonable and permissible under the FOIA. *Jud. Watch, Inc. v. U.S. Dept. of Hous. and Urb. Dev.*, 20 F. Supp. 3d 247, 254–55 (D.D.C. 2014) (finding it permissible for an agency to rely on subject matter experts to conducted individualized searches for documents when responding to FOIA requests); *Fox News Network, LLC v. U.S. Dep't*

[3] To improve its management of FOIA requests, the agency recently began the process of transitioning each of FDA's FOIA components into a unified office. Though this transition is only in its preliminary stages and has not been fully implemented, FDA does not anticipate changes within the FOIA components themselves because reviewers in each FDA component possess unique subject-matter expertise over the information regularly maintained by their respective center and component-specific disclosure regulations. Accordingly, even when the transition is complete, FDA's FOIA program will continue to operate in a decentralized manner with each FOIA component, like CBER's disclosure office, retaining its current supervisors, staff, and contractors as well as all disclosure responsibilities over their respective center-maintained information.

of Treasury, 739 F. Supp. 2d 515, 533–34 (S.D.N.Y.2010) (expressly affirming as reasonable a "decentralized method of processing FOIA requests.")

Congress has further recognized that processing requests on a *strict* "first-in, first-out" (FIFO) basis could result in a lengthy delay for simple requests that are forced to await the processing of complex requests, and such delay would only increase agency backlog. H. Rep. No. 104-795, at 23. Accordingly, Congress permitted, and even encouraged, agencies to implement multi-track systems (5 U.S.C. § 552(a)(6)(D)(i)), acknowledging that such systems would naturally allow simpler requests to be processed ahead of more complex ones that may have been received earlier. S. Rep. No. 104-272, at 17 (further recognizing that agencies may also have more than just simple and complex tracks). Congress also noted that agencies should exercise due diligence "within each track," suggesting that agencies should not have to delay processing a simple request simply because an earlier-received complex request has not closed. *See* H. Rep. No. 104-795, at 23; S. Rep. No. 104-272, at 17. Therefore, it is evident that by authorizing agencies to implement multi-track processing, Congress intended FIFO to be applied to the requests in each track, and not, as Plaintiff suggests, a single (or even multi-) agency-wide processing track.

As explained in FDA's motion for stay, ECF Nos. 14 and 17, CBER's FIFO or "first-in, first processed" FOIA processing and implementation of multi-track processing are sufficient to show due diligence under *Open America*. *See Energy Future Coal. v. Off. Of Mgmt. & Budget*, 200 F. Supp. 3d 154, 162. CBER is the FDA component most likely to possess records responsive to Plaintiff's request and CBER's disclosure office is the office with the subject matter-expertise to evaluate those records for disclosure. Supp. Burk Decl. ¶¶ 2-3. Moreover, the Center's multi-track system of processing falls well within the bounds of FOIA (5 U.S.C. § 552(a)(6)(D)),

Congressional intent, and FDA's own disclosure regulations (21 C.F.R. § 20.43). CBER queues are based on the amount of work and/or time required for a request to be processed. *See* Supp. Burk Decl. ¶ 17 (explaining CBER's queues, including the scope of disclosure work necessary and/or the time required to process requests in each queue, *e.g.*, requests in CBER's Fast Track seek records that were previously reviewed and redacted or information that is already publicly available). As Plaintiff notes, Pl. Supp. Br. at 13-14, the speed at which requests in each of these queues may be processed in relation to other requests in different queues (and even other requests in the same queue) will differ, *see* Supp. Burk Decl. ¶¶ 18 and 24; however, CBER assigns requests for processing on a first-in, first-processed basis and thus ensures that requests in each track *begin* processing in the order in which they are submitted to the queue. *Id.*

Notably, Plaintiff cites to very little legal precedent to support its argument that FIFO must be assessed at the agency level. Pl. Supp. Br. at 7-8. In one case, *Nightingale v. U.S. Citizenship and Immigration Servs.*, 507 F. Supp. 1193, 1202 (N.D. Cal. 2020), the court found that the Department of Homeland Security and its component agencies (collectively, "DHS") had established a pattern of unreasonable delay in responding to FOIA requests in part because DHS had repeatedly relied on a patchwork of short-term fixes (*e.g.*, overtime, staff details, and contract support) and not more long-term solutions such as requesting funding from Congress. *Id.* at 1206. As the Court noted, DHS did not dispute that there was a multi-year systemic failure across the department to make timely determinations on FOIA requests, and that more aggressive enforcement policies made an increasing FOIA workload predictable and expected. *Id.*

Unlike the defendants in *Nightingale*, FDA has aggressively implemented large-scale changes to CBER's FOIA operations, including hiring additional staff and contractors, first to meet the obligations of *PHMPT I*, then again for *PHMPT II*, and now engaging a third time in a massive

effort to address FOIA backlogs agency-wide. Supp. Burk Decl. ¶¶ 32, 34-36. CBER also implemented sweeping organizational and work process changes to comply with the court-ordered productions. *Id.* ¶ 32. Further, as described above and in FDA's initial stay motion, ECF Nos. 14 and 17, CBER's current FOIA workload was unpredictable because it resulted from an unprecedented series of court orders and a sudden surge in the volume of requests due to the COVID-19 pandemic that marked a significant departure from the prior status quo. As Plaintiff is well aware, Plaintiff and Plaintiff's counsel have played a major role in the unprecedented shift in and growth of CBER's FOIA backlog. *Id.* ¶¶ 11 and 38. Despite the continuous challenges, FDA and CBER's disclosure office consistently marshalled additional resources and staff in an effort to meet their statutory and court-imposed obligations.

With respect to Plaintiff's analysis of FDA's public FOIA data, FDA's data is not a one-for-one reflection of the agency's efforts processing FOIA requests, including CBER's. Under the Electronic FOIA Amendments of 1996, federal agencies must submit an annual report to the U.S. Attorney General detailing certain statistical data about the agency's processing of FOIA requests from the preceding fiscal year. 21 U.S.C. § 552(e)(1) and (e)(2). Per its statutory obligations, FDA collects the required statistical data and submits the data to HHS, which then prepares an annual report, incorporating data from all HHS component agencies for final submission to the Attorney General. HHS then publishes the final annual report and underlying statistical data, including FDA-specific data, on its website for public viewing. *See e.g.*, HHS Fiscal Year 2024 Freedom of Information Annual Report, https://www.hhs.gov/foia/reports/annual-reports/2024/index.html and FY 2024 Raw Data, https://www.hhs.gov/foia/reports/annual-reports/fy-2024-raw-data.html. When preparing the annual reports, DOJ directs all federal agencies to break down their data into three processing tracks as outlined by the FOIA: Simple, Complex, and Expedited. *See* 5 U.S.C.

§ 552(a)(6)(E)(i); Department of Justice Annual FOIA Report Handbook, at 17, https://www.justice.gov/d9/2024-10/DOJ%20Handbook%20for%20Agency%20Annual%20FOIA%20Reports%20%282024%20update%29.pdf. Agencies with more than those three tracks are further instructed to re-allocate all requests into either the simple or complex track, "whichever best matches the type of requests handled in those additional tracks." Department of Justice Annual FOIA Report Handbook, at 17. Accordingly, FDA's annual FOIA data does not reflect the statistical details of its internal component multi-track systems.

FDA is also required to publish a public FOIA log of every request for records received by the agency. 21 C.F.R. § 20.40(c). FDA publishes these logs on a monthly and annual basis, reflecting both the requests that were received and/or closed during the respective period. *See* FDA FOIA Logs, https://www.fda.gov/regulatory-information/freedom-information/fda-foia-logs. Because this data can be used to support FDA's annual report, FDA's public FOIA logs do not account for the agency's internal component multi-track systems and instead re-allocate each request into either the simple or complex track. *See* Department of Justice Annual FOIA Report Handbook, at 17. The agency is not required to publish data on its internal multi-track systems.

Using this data, Plaintiff now attempts to highlight presumed discrepancies in the agency's FOIA processing. But as explained, the data itself is not a one-for-one reflection of agency processing because it does not address FDA's multi-track processing. For example, Plaintiff asserts that FOIA Request No. 2024-965 (at issue here) was "one of twenty-nine requests FDA received and perfected on January 29, 2024," and "of those twenty-nine, FDA closed seven within 20-days, three more by day 23, and many others between 37 and 283 days." Pl. Supp. Br. at 8. Plaintiff then states that "FDA closed twenty-two (76%) of the requests within one year, two more received a partial response," but five, including Plaintiff's request, remain open. *Id.* Yet, Plaintiff

ignores that, unlike other requests FDA received on January 29, 2024, Plaintiff's request sought records maintained by CBER, whose processing capabilities, as Plaintiff is aware, have been significantly slowed by unprecedented production orders in *PHMPT I* and *PHMPT II*. *See* Compl., ECF No. 1, ¶ 6 (describing Plaintiff's FOIA request seeking records related to COVID-19 vaccines). In addition, Plaintiff's request was assigned to CBER's Complex Track, meaning the request has an estimated processing time of more than sixteen hours, likely involves voluminous potentially responsive records, and will likely require extensive time to locate, review and/or redact records. *See id*. ¶¶ 17 and 39. Most importantly, unlike the other requests received on January 29, 2024, Plaintiff's request is currently behind 470 other requests in the CBER's Complex Track, including hundreds of this Plaintiff's own requests (at least 13 of which are also in litigation). Supp. Burk Decl. ¶¶ 29, 38-39.

Plaintiff's supplemental brief continues with further conjecture and incorrect assumptions, asserting alleged patterns in FDA's data where later-received requests are processed ahead of Plaintiff's, and arguing that if FDA were processing FIFO, earlier-perfected requests would not be left unsearched while later-perfected requests are closed. Pl. Supp. Br. at 9-12. Notably, however, the agency's public FOIA information does not reflect the status of requests that are in process or a complete picture of how the requests were closed. For example, the public FOIA information does not account for the time an FDA component spends communicating with a requestor to obtain clarity or to negotiate the scope of the request, nor does it identify when a request remains open as a result of ongoing litigation (*e.g.*, where the FDA component is making monthly productions pursuant to a court-imposed or party-negotiated schedule, or processing of responsive records is complete but briefing or settlement negotiations are ongoing). *See e.g.*, Supp. Burk Decl. ¶¶ 18, 24, and 25. At any given time, FDA's FOIA program requires multiple staff, across multiple agency

components, to be processing hundreds of FOIA requests across multiple tracks. *See* Schlaifer Decl. ¶ 8. This process ensures fairness to the hundreds of requests in CBER's queues that were not submitted by Plaintiff, that seek only a handful of discrete pages rather than millions, and whose requestors lack the resources to pursue litigation. When viewed in the simplest terms, Plaintiff's analysis advocates in its own self-interest and for a rigidity in FOIA processing that would significantly disadvantage other FOIA requestors. Such analysis is not an appropriate tool for evaluating whether FDA has exercised the necessary due diligence to warrant a stay under *Open America*.

Finally, Plaintiff's argument comes full circle by again arguing that FDA must exercise due diligence in responding to Plaintiff's request and that FDA is required to show that Plaintiff's request has not been "bypassed in practice." Pl. Supp. Br. at 15. FDA has already explained, however, that it has exercised due diligence with respect to Plaintiff's request. *See* ECF No. 14, at 6-7; ECF No. 17, at 15 (detailing the steps CBER's disclosure office undertook, including identifying the appropriate queue placement, determining Plaintiff's request should be placed in the Complex Track, and evaluating whether a motion for stay was necessary). Further, there is no requirement that FDA show due diligence with respect to FIFO processing of all FOIA requests agency-wide, only that it must show due diligence "within each track." *See* pp. 7-9 *supra*. Plaintiff continues its not-so-subtle attempt to elevate its request to the front of the queue simply because Plaintiff has the means to file the present lawsuit. *See also* Pl. Supp. Br. at 17. But as FDA previously noted, courts have routinely rejected the notion that the mere filing of a lawsuit, absent a showing of "exceptional need or urgency," should expedite processing of a FOIA request. *See Open America*, 547 F.2d at 616; *Cohen v. FBI*, 831 F. Supp. 850, 854 (S.D. Fla. 1993); *see also*, *Informed Consent Action Network v. FDA*, Civ. A. No. 23-0219 (RBW) (D.D.C.), Status Conf.,

ECF No. 33, at 6 (Jan. 13, 2026) (acknowledging "that it would be inappropriate . . . to jump this case over the other cases that were filed earlier"). Plaintiff has shown no exceptional need or urgency, and, thus, should not be an exception here.

Recognizing the ongoing unprecedented demands on CBER's FOIA office, courts have continued to grant and extend stays in other pending FOIA matters involving CBER records. *See* Supp. Burk Decl. ¶ 38, detailing the following and more; *Wright v. Dep't of Health & Human Servs.*, Civ. A. No. 22-1378 (RC) (D.D.C.), Mem. Op. at 8, ECF No. 61 (July 31, 2025) (extending 18-month stay an additional six months); *Informed Consent Action Network v. FDA*, Civ. A. No. 23-0219 (RBW) (D.D.C.), Status Conf. (Jan. 13, 2026) (continuing stay until November 5, 2026); *Children's Health Def. v. FDA*, Civ. A. No. 23-2316 (LLA) (D.D.C.), Min. Order (Sept. 16, 2025) (extending stay 18 months, until February 22, 2027, with status reports every 90 days); *Children's Health Def. v. CDC*, Civ. A. No. 23-0431 (TMN) (D.D.C.), Min. Order (July 28, 2025) (denying Plaintiff's request to lift stay first entered on July 24, 2024); *Solomon v. Dep't of Health & Human Servs.*, Civ. A. No. 24-0572 (RBW) (D.D.C.), Order, ECF No. 29 (Jan. 13, 2026) (continuing stay until November 5, 2026); *Informed Consent Action Network v. FDA*, Civ. A. No. 24-1761 (AHA) (D.D.C. June 17, 2024); Order, ECF No. 18 (Nov. 20, 2024) (granting stay for eight months until July 21, 2025); Joint Status Report, ECF No. 19 (July 23, 2025) (requesting extension of stay for 18 months, pending); *Informed Consent Action Network v. FDA*, Civ. A. No. 24-1905 (JDB) (D.D.C.), Order, ECF No. 20 (Aug. 7, 2025) (extending stay an additional six months, with joint status report due by Feb. 9, 2026); *Informed Consent Action Network v. FDA*, Civ. A. No. 24-1906 (CRC) (D.D.C. June 28, 2024), Min. Order (Jan. 30, 2026) (extending stay until October 16, 2026); Joint Status Report, ECF No. 24 (January 16, 2026) (pending request for extension of stay); *Informed Consent Action Network v. FDA*, Civ. A. No. 25-0824 (AHA) (D.D.C.

Mar. 18, 2025), ECF No. 20 (Jan. 29, 2026) (granting 18-month stay until and including April 16, 2027); *Informed Consent Action Network v. FDA*, Civ. A. No. 25-0827 (JMC) (D.D.C. Mar. 19, 2025), ECF No. 18 (Aug. 28, 2025) (granting 6-month stay, to Feb. 27, 2026, with joint status report due at that time). *But see Informed Consent Action Network v. FDA*, Civ. A. No. 24-1555 (RCL) (D.D.C. May 25, 2024), Order, ECF No. 25 (Dec. 23, 2025) (declining to extend stay).

FDA continues to face exceptional circumstances and continues to exercise due diligence. The burdens of *PHMPT II* remain extraordinarily heavy, and FDA continues its efforts to allocate its limited resources efficiently. To assist FDA in meeting the *PHMPT II* court's production deadline and ensure fairness to other FOIA requesters whose earlier requests are pending in CBER's Complex Track, the stay should be granted for at least eighteen months. An eighteen-month stay will allow CBER's disclosure office to not only complete its production in *PHMPT II*, but provide the Center additional time to further process its FOIA backlog, including in CBER's Complex Track, and to process Plaintiff's request in the fairest manner to both Plaintiff and the numerous other requestors who are awaiting responses. *See* Supp. Burk Decl. ¶ 39 (Plaintiff's request is positioned behind 470 other FOIA requests, including hundreds of Plaintiff's other requests (13 of which are also in litigation)).

To that end, Defendants respectfully request that the Court impose a stay for at least eighteen months, through and including June 25, 2027, and propose filing a subsequent status report within two weeks after the end of the eighteen-month period—*i.e.* July 9, 2026—outlining their proposal for further proceedings in this case.

* * *

Date: January 30, 2026

Respectfully submitted,

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