

**UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION**

CARETOLIVE,)	
a not-for-profit corp.,)	
)	Civil No. 2:08-CV-00005
Plaintiff,)	
)	JUDGE FROST
v.)	
)	MAGISTRATE JUDGE KING
U.S. FOOD and DRUG)	
ADMINISTRATION,)	
)	
Defendant.)	

**DEFENDANT UNITED STATES FOOD AND DRUG ADMINISTRATION'S
MOTION TO STAY PROCEEDINGS**

Defendant United States Food and Drug Administration moves to stay proceedings in the above-captioned matter pursuant to 5 U.S.C. § 552(a)(6)(C). The grounds for this motion are set forth in the attached Memorandum of Law.

Respectfully submitted,

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MEMORANDUM OF LAW

INTRODUCTION

Plaintiff CareToLive¹ brought this action against the United States Food and Drug Administration (“FDA” or “the Agency”), Department of Health and Human Services. The Complaint pertains to a Freedom of Information Act (“FOIA”) request from Kerry Donahue of Bellinger & Donahue, Attorneys at Law, made by letter dated August 15, 2007. See Letter from Bellinger & Donahue, dated August 15, 2007, (“FOIA request”), attached as Exhibit 1 to Declaration of Frederick J. Sadler, dated February 13, 2008, (“Sadler Decl.”), attached as Exhibit A.²

Defendant FDA respectfully moves for a twenty month stay of the above-captioned FOIA proceeding, pursuant to 5 U.S.C. § 552(a)(6)(C), to allow FDA time to process Plaintiff’s FOIA request in accordance with FDA’s first-in/first-out, multi-track processing system. The declarations supporting this motion demonstrate exceptional circumstances sufficient to justify a stay of proceedings. Open America v. Watergate Special Prosecution Force, 547 F.2d 605 (D.C. Cir. 1976) (“Open America”). Such a stay would allow FDA to process Plaintiff’s FOIA request in a manner not prejudicial to the thousands of FOIA requesters with requests submitted prior to Plaintiff’s request. Congress could not have “intended, by fixing a time limitation on agency action and according a right to bring suit . . . to grant an automatic preference by the mere action

¹The Court determined for purposes of reassigning this case to the docket of Judge Frost that it was related to CareToLive v. Andrew von Eschenbach et al., U.S. District Court for the Southern District of Ohio, Eastern Division, Case No. C2-07-729. See Order Reassigning Case (Doc. 4.)

²FDA notes that the FOIA request was not made in Plaintiff’s name. FDA accepts, for purposes of argument, that Bellinger & Donahue transmitted the FOIA request on Plaintiff’s behalf.

of filing a case.” Id. at 614.

STATEMENT OF FACTS

I. Plaintiff’s FOIA Request

On September 11, 2007, FDA’s Division of Freedom of Information (“DFOI”) received a FOIA request from Plaintiff dated August 15, 2007.³ Sadler Decl. ¶ 10. The request sought the following:

A copy of all letters written to the FDA (or prepared by the FDA) and purported to be from Dr. Scher, Dr. Hussain and Doctor Fleming in between March 29th 2007 and April 30th of 2007, regarding the BLA submitted for Provenge also known as Sipuleucel-T including the envelope or other means of communication whereby the FDA received such letters and a copy of any record of those letters then being disclosed to any media or other persons or specifically a publication called “The Cancer Letter”, including the means of communication to the Cancer Letter of the Scher, Hussain and Fleming letters from the FDA or its employees to outside persons, publications or companies.

Sadler Decl., Ex. 1 at 1.

DFOI logged-in the FOIA request and assigned it reference number “2007-8316”, identifying it as the eight thousand, three hundred and sixteenth (8,316th) FOIA request FDA received in 2007. Sadler Decl. ¶ 10. DFOI advised Plaintiff by letter dated the same day that the FOIA request had been received. Sadler Decl. ¶ 11; Letter from Shera S. Behram to Bellinger & Donahue dated September 11, 2007, attached to Sadler Decl. as Exhibit 2.

FDA regulates more than \$1 trillion of commerce each year; its jurisdiction includes drugs, foods, animal feeds, biologics, veterinary medicines and medical devices. Declaration of Nancy B. Sager, dated February 13, 2008, (“Sager Decl.”) ¶ 15, attached as Exhibit B. One

³ The delay between the date of Bellinger & Donahue’s letter and receipt by DFOI occurred because Plaintiff improperly sent the request to the agency’s Cincinnati district office rather than to DFOI. Per 21 C.F.R. 20.40(a), all FOIA requests must be received in DFOI in order to be logged and processed. The request was forwarded from the Cincinnati district office to DFOI on or around September 11, 2007. (Sadler Decl. ¶ 10, n.1).

consequence of this broad oversight is an extraordinary volume of FOIA requests. To process them as efficiently as possible, FDA has established a decentralized system for responding to FOIA requests, whereby DFOI forwards individual requests to the FDA component(s) most likely to possess responsive records. Sadler Decl. ¶ 8; Sager Decl. ¶ 7. Accordingly, DFOI forwarded Plaintiff's request to the Access Litigation and Freedom of Information Branch in FDA's Center for Biologics Evaluation and Research ("CBER") (because the FOIA request sought records relating to an unapproved biological product regulated by that Center) and the Office of the Commissioner ("OC"), Office of the Executive Secretariat (because the FOIA request sought records relating to agency correspondence). Sadler Decl. ¶¶ 12, 13. CBER responded with documents on November 6, 2007. Complaint ¶ 4; Sadler Decl. ¶ 12. OC's Office of the Executive Secretariat responded to the request through DFOI on January 24, 2008, stating that it had not located any responsive records. Sadler Decl. ¶ 13; Letter from Theola Myo Khin dated January 24, 2008, attached to Sadler Decl. as Exhibit 3.

After initially forwarding the request to CBER and OC, DFOI also transmitted the FOIA request to the Division of Information Disclosure Policy ("DIDP") in FDA's Center for Drug Evaluation and Research ("CDER"). Sadler Decl. ¶ 14. DFOI did so because, after consultation with CBER, it appeared that CDER might also have records responsive to the request. Id. DIDP received Plaintiff's FOIA request on October 15, 2007. Sager Decl. ¶ 28. DIDP assigned it to the "Complex Track" because DIDP determined that Plaintiff's request sought documents not readily available and would require DIDP to search for and possibly redact documents. Sager Decl. ¶ 29. DIDP attempted to contact Plaintiff's counsel on December 4, 2007, leaving a telephone message stating that DIDP follows a first-in/first-out process for responding to FOIA

requests, and that Plaintiff's FOIA request would be processed accordingly. Id. DIDP left this message again on December 31, 2007. Id.

II. DIDP's System for Processing FOIA Requests

CDER is the center within FDA responsible for the regulation of most human drugs and therapeutic biological products. Sager Decl. ¶ 19. As of January 31, 2008, CDER had approximately 3,420 FOIA requests awaiting processing. Sager Decl. ¶ 20. Once at DIDP, FOIA requests which can be answered quickly with readily available documents, and which do not require any searching or redaction, are considered "simple" and generally are processed on a faster track (known as the "Simple Track"), as opposed to "complex" requests that follow a slower processing track (known as the "Complex Track"). Sager Decl. ¶ 8. DIDP staff generally process requests in each track using a first-in/first-out system. Id.

Requests assigned to the Simple Track do not require DIDP personnel to search for or redact documents, generally because DIDP has previously reviewed and redacted the responsive documents (e.g., because they were responsive to a prior FOIA request); the requested documents are publicly available; or it is clear from the face of the request that CDER has no responsive documents. Sager Decl. ¶ 9. DIDP then either makes copies of previously processed documents and provides them to the requester; directs the requester to documents publicly available; or notifies the requester that CDER has no responsive documents. Sager Decl. ¶ 10. DIDP may, when appropriate, divide a single request into simple and complex parts, allocating them between the two tracks. Sager Decl. ¶ 9.

Any requests not considered appropriate for the Simple Track are placed in the Complex Track. Sager Decl. ¶ 11. Generally, as requests in the Complex Track move to the head of the

queue, they are assigned to a specific DIDP employee for processing. Id. Multiple DIDP staff members may be assigned to work on a single complex request, however, if DIDP anticipates that the request will necessitate extensive searching for documents in different parts of CDER. Id. Such requests often embrace voluminous materials, with correspondingly lengthy search and redaction times to prepare them for release. Id. Requests of this nature often require substantive input from supervisory staff to determine both the scope of the search and the ultimate releasability of the records and, once the documents have been located and redacted, frequently a team leader conducts a quality control review to ensure that the responsive documents have been properly prepared for public disclosure. Sager Decl. ¶¶ 11-12.

DIDP may need to search, or contact individuals and direct them to search, numerous agency files in order to respond to requests in the Complex Track. Sager Decl. ¶ 12. DIDP then conducts a preliminary review of the records collected to verify that they are responsive to the request. Id. Next, DIDP performs a page-by-page, line-by-line review of the responsive documents to determine whether any can be released and whether any FOIA exemptions apply. Id. DIDP then redacts exempt material. Id. This review ensures that the FOIA exemptions have been properly applied, that no releasable material has been withheld, and that no material meriting protection will be released. Id. Finally, DIDP prepares and delivers copies of the responsive, redacted documents to the requester. Id.

DIDP works to promote efficiency in its system for processing requests in the Complex Track. First, several requests can seek the same, or closely related, records. Once a request for certain records rises to the top of the Complex Track, DIDP processes responses to requests (or portions of requests) that seek the same, or closely related, information, at the same time. This

permits DIDP to provide at least some documents to requesters further back in the queue sooner than they might otherwise have received them – though the response may be only partial. Sager Decl. ¶ 11. Second, if a request is delayed during processing, the DIDP personnel working on it may begin work on the next request in line. Sager Decl. ¶ 14. Complex requests can encounter processing delays for reasons including, but not limited to, the following: determining exemptions’ applicability; locating missing records; or consulting with other government agencies regarding the release of documents. Id. If DIDP completes work on the next request during the waiting period, DIDP releases the responsive records at that time. Id. DIDP uses this approach to reduce the processing time for many FOIA requests. Id.

ARGUMENT

FOIA entitles FDA to a stay of proceedings to permit it to respond fully to Plaintiff’s FOIA request. Although federal agencies ordinarily must respond to document requests within twenty working days (see 5 U.S.C. § 552(a)(6)(A)), this time frame is subject to exceptions. Specifically, FOIA permits courts to grant agencies additional time to process a FOIA request: (1) “If the Government can show exceptional circumstances exist;” and (2) “the agency is exercising due diligence in responding to the request.” 5 U.S.C. § 552(a)(6)(C)(i). In Open America v. Watergate Special Prosecution Force, 547 F.2d 605, 616 (D.C. Cir. 1976), the leading case on section 552(a)(6)(C)(i), the United States Court of Appeals for the District of Columbia held that a court may grant a federal agency additional time to review records “when an agency . . . is deluged with a volume of requests for information vastly in excess of that anticipated by Congress, when the existing resources are inadequate to deal with the volume of such requests within the time limits of subsection (6)(A), and when the agency can show that it

‘is exercising due diligence’ in processing the requests.” Stays under 5 U.S.C. § 552(a)(6)(C)(i) have become known as “Open America stays” and are used explicitly as “safety valves” to assist agencies struggling under FOIA’s burdens. *E.g.*, Appleton v. Food and Drug Admin., 254 F. Supp. 2d 6, 8 (D.D.C. 2003) (describing section 552(a)(6)(C)(i) as a “‘safety valve,’” quoting Open America, 547 F.2d at 610).

The Electronic Freedom of Information Act Amendments of 1996 (“EFOIA”)⁴ and subsequent case law elaborated upon section 552(a)(6)(C)(i)’s basic requirements of “exceptional circumstances” and “due diligence.” To satisfy FOIA’s exception to the twenty-day rule, FDA must demonstrate: (1) exceptional circumstances (typically a high volume of information requests met by insufficient resources) (*e.g.*, Open America, 547 F.2d at 616); (2) reasonable progress in reducing any backlog of requests accumulated due to a predictable agency workload (*e.g.*, Leadership Conference on Civil Rights v. Gonzales, 404 F. Supp. 2d 246, 259 (D.D.C. 2005) (even if workload is predictable, exceptional circumstances can exist if there is reasonable progress in reducing backlog, quoting 5 U.S.C. § 552(a)(6)(C)(ii)); and (3) good faith and due diligence in complying with FOIA requests in as short a time as possible (*e.g.*, Center for Biological Diversity v. Gutierrez, 451 F. Supp. 2d 57, 70 (D.D.C. 2006) (courts generally find exceptional circumstances excuse delays when an agency makes good-faith efforts and exercises due diligence in processing requests and appeals on first-in/first-out basis)).

Under these circumstances, it is not uncommon for a court to grant a stay resulting in a span of several years between the filing of the FOIA request and the agency’s document production. *See, e.g.*, Elec. Frontier Found. v. United States Dep’t of Justice, 2007 U.S. Dist.

⁴ EFOIA Amend. of 1996, Pub. L. No. 104-231; § 7(c), 110 Stat. 3048 (codified as amended at 5 U.S.C. § 552(a)(6)(C)(ii)). *See infra* at p. 15.

LEXIS 33396, *25 (D.D.C. May 7, 2007) (granting a stay of one year, with the possibility of an extension); Elec. Privacy Info. Ctr. v. United States Dep't of Justice, 2005 U.S. Dist. LEXIS 18876, *12 (D.D.C. Aug. 31, 2005) (giving the FBI a stay until August 31, 2005 to respond to a FOIA request originally dated June 22, 2001, and clarified by letter dated August 8, 2001); Piper v. United States Dep't of Justice, 339 F. Supp. 2d 13, 16 (D.D.C. 2004) (discussing a stay of two years given to the FBI); Appleton, 254 F. Supp. 2d at 11 (granting FDA's motion for stay pending completion of search and production of documents); Judicial Watch of Florida, Inc. v. United States Dep't of Justice, 102 F. Supp. 2d 6, 9 & n.1 (D.D.C. 2000) (discussing an order giving the FBI until June 8, 2000 to respond to a request dated July 15, 1997); Emerson v. CIA, 1999 U.S. Dist. LEXIS 19511, * 4 (D.D.C. Dec. 16, 1999) (giving the State Department until September 6, 2000 to respond to a request dated three years prior); Edmond v. United States Attorney, 959 F. Supp. 1, 4 (D.D.C. 1997) (giving the U.S. Attorney's Office until April 1, 1998 to respond to a request filed August 14, 1992); Jimenez v. FBI, 938 F. Supp. 21, 31 (D.D.C. 1996) (granting FBI's request for stay and permitting it over four years to respond to plaintiff's FOIA request).

As discussed below, the supporting declarations in this case demonstrate all three factors necessary for FDA to be granted an Open America stay.

I. Exceptional Circumstances Render FDA Unable to Meet FOIA's 20-day Period

Exceptional circumstances exist when an agency confronts vast numbers of requests for information disclosure, at a level unanticipated by Congress, with insufficient resources to manage those requests. Open America, 547 F.2d at 616; see also Appleton v. FDA, 254 F. Supp. 2d 6, 8-9 (D.D.C. 2003). FDA generally, and DIDP in particular, receive a tremendous number

of FOIA requests annually. Additionally, DIDP receives large numbers of court-related and Congressional document requests and is also responsible for compliance with new legislative enactments. Though DIDP has made great efforts to improve its capability to answer FOIA requests in a timely manner—and has reduced its backlog by approximately fifty per cent (50%) over the past five years—DIDP's resources have been insufficient to match a volume of requests (and a level of complexity of those requests) which Congress could not have anticipated. Plaintiff's position in the instant case resembles that of other FOIA requesters caught in the unfortunate gap between FOIA's aspirations and the resources allocated to agencies for FOIA work.

A. DIDP Receives a High Volume of FOIA and Other Record Requests

The declarations supporting this motion establish the high volume of FOIA requests received by FDA and, more specifically, by DIDP. The declarations also establish the heavy litigation demands, the large number of Congressional document requests, and the significant workload generated by new legislative enactments faced by DIDP.

1. DIDP receives a high volume of FOIA requests

FDA received 11,400 FOIA requests agency-wide in 2007 (approximately 950 per month). Sadler Decl. ¶ 5. FDA processed 15,742 FOIA requests in 2006 and 17,295 requests in 2007. Id.

DIDP received 5,310 FOIA requests in 2003; 5,156 requests in 2004; 4,050 requests in 2005; 3,335 requests in 2006; and 2,888 requests in 2007. Sager Decl. ¶ 16. In 2007, approximately twenty-five per cent (25%) of all of FDA's FOIA requests were assigned to DIDP. Id. Based on these numbers, DIDP averaged 346 *new* FOIA requests per month from

2003 through 2007.

Raw numbers of annual FOIA requests fail to reflect their size or complexity. First, because CDER is the agency component responsible for the regulation of most human drugs and therapeutic biological products, many records kept within CDER include information that is exempt from disclosure as trade secret information, confidential commercial information, personal privacy information, and/or deliberative process information. Sager Decl. ¶ 19. Careful pre-disclosure review of these records is therefore critical, legally required and extremely time-consuming. Second, many FOIA requests are actually multiple, separate queries for documents. Sager Decl. ¶ 18. For example, a FOIA request submitted on July 30, 2007, sought 992 individual MedWatch forms.⁵ DIDP estimates that, once that request reaches the top of the Complex Track and the responsive documents are retrieved, it will require one full-time employee approximately four weeks to review the documents and redact exempt information. Id. Out of 181 FOIA requests received by DIDP in November 2007 alone, 7 contained 15 or more separate requests; 5 contained 10-14 separate requests; 23 contained 5-9 separate requests; and 30 contained 2-4 requests. Id. Realistically, then, DIDP actually received at least 300 requests during November 2007. Both from volume and complexity perspectives, DIDP's FOIA request workload is vastly in excess of that anticipated by Congress.

The average number of FOIA requests DIDP received in 2007 was 240 requests per month. Sager Decl. ¶ 17. While that number represents a decline from historical norms, it does not indicate a corresponding decrease in DIDP's workload because it does not reflect: (1)

⁵ MedWatch forms (Form FDA 3500) are used by healthcare professionals, consumers, and patients for reporting to FDA serious adverse events, potential and actual product use errors, and product quality problems associated with the use of FDA-regulated products.

DIDP's proactive disclosure efforts (resulting in fewer FOIA requests); (2) DIDP's education and outreach efforts (resulting in fewer, and narrower, new FOIA requests); or (3) DIDP's existing backlog, which actually determines the number of requests being processed by DIDP at any given point in time. DIDP continually posts drug approval packages, approval letters, and warning letters; this effort reduces the number of incoming FOIA requests each year—but not the amount of FOIA work. Sager Decl. ¶ 27(d). For example, DIDP has reduced the average review time for “new molecular entity” approval packages (from 11 ½ weeks in calendar year 2005 to approximately 8 weeks in calendar year 2007) and decreased the time in which they are posted, generating an annual reduction of approximately 200 FOIA requests for approval packages over the last two years. Id. DIDP also actively engages in customer education and outreach efforts to assist large volume FOIA requesters. DIDP identified and worked with one such requester to reduce since 2003 its annual number of FOIA requests by about 900. Sager Decl. ¶ 27(e).

Finally, current monthly FOIA request averages do not reflect the actual burden of FOIA requests near the head of DIDP's queue. To illustrate, in November 2007, just one month after DIDP received Plaintiff's FOIA request, a May 2005 FOIA request rose to the top of DIDP's Complex Track. Sager Decl. ¶ 17. DIDP duly identified approximately 21,000 pages of responsive documents for this 2005 request, with processing anticipated to require an additional 27 weeks of full-time effort by one DIDP employee (to review the documents and redact exempt information). Id. Under DIDP's first-in/first-out processing system, Plaintiff's August 2007 FOIA request cannot be processed until DIDP completes the May 2005 request and all other requests pending in the Complex Track submitted before Plaintiff's request.

2. DIDP is subject to unusually heavy litigation demands

Agency litigation also places enormous demands on the division. Congress understood that the number of courts' requests for records, as well as size and complexity of requests being processed, and the amount of classified material involved, may be relevant to a determination of whether exceptional circumstances exist. See H.R. Rep. No. 104-795, pt. IV.B., at 18-19 (1996), 1996 USCAAN 3448, 3468; Wilderness Soc'y v. U.S. Dep't of Interior, No. 04-0650, 2005 U.S. Dist. LEXIS 20042, *21 (D.D.C. Sept. 12, 2005).

During 2007, DIDP collected, reviewed, redacted, and indexed tens of thousands of pages of documents related to multiple FOIA lawsuits, third-party subpoenas, and discovery requests in cases in which FDA is a party. Sager Decl. ¶ 21. DIDP assigned five full-time employees solely to those matters, which include: (1) In Re Fosamax Product Liability Litigation, MDL Docket No. 1742 (S.D.N.Y.), in which a third-party subpoena was served on FDA (on or about February 5, 2007), and DIDP reviewed, redacted and indexed approximately 1,300 pages of documents; (2) In Re Seroquel Product Liability Litigation, MDL Docket No. 6:06-md-1769 (M.D. Fla.), in which DIDP reviewed, redacted and indexed approximately 3,000 pages of documents under a third-party subpoena served on FDA (on or about May 10, 2007); (3) Jerome Stevens Pharmaceuticals, Inc. v. Food and Drug Administration, Case No. 1:02-cv-01939 (D.D.C.), in which DIDP reviewed, redacted, and indexed approximately 3,000 pages of documents in response to discovery requests; (4) Securities and Exchange Commission v. Richard F. Selden, Case No. 05-cv-00476 (D.D.C.), in which DIDP reviewed, redacted, and indexed approximately 12,000 pages under a third-party subpoena; and (5) Bloomberg L.P. v. FDA; Case No. 06-cv-6552 (S.D.N.Y.), a FOIA lawsuit, in which DIDP reviewed, redacted, and

indexed approximately 5,000 pages of documents. See also Sager Decl. ¶ 21 (providing further examples).

Litigation-related document productions stretching already thinly-spread resources can constitute exceptional circumstances justifying an Open America stay. E.g., Wilderness Soc’y, 2005 U.S. Dist. LEXIS 20042, at *21 (resources devoted to declassification and requests by courts or administrative tribunals can be bases for finding exceptional circumstances); Bower v. FDA, 2004 U.S. Dist. LEXIS 18369, *5 (D. Me. Aug. 30, 2004) (FDA’s “enormous litigation demands” contributed to findings of exceptional circumstances); Edmonds v. FBI, No. 02-1294, 2002 U.S. District LEXIS 26578, at *5 (D.D.C. Dec. 3, 2002) (FOIA staff’s time spent on administrative appeals, litigation and “large projects” contributed to finding of exceptional circumstances).

3. Congressional requests add to DIDP’s burden

Document requests made by Congress to FDA have been another highly significant part of DIDP’s workload. Sager Decl. ¶ 22. Although these requests are not made under FOIA and are not processed in FOIA’s tracks, they are prioritized because they originate from Congress; and the same group of employees processes them,⁶ resulting in fewer available resources for FOIA-specific processing. Id. During the past 12 months, including the pendency of Plaintiff’s FOIA request, DIDP has reviewed approximately 44,000 pages of documents for Congress; during a 3-month period in 2006, DIDP reviewed more than 125,000 pages for a single Congressional subpoena; and during a 12-month period between August 2004 and August 2005, DIDP produced over 100,000 pages for Congress. Id. The large number of Congressional

⁶ This ensures continuity of experience and approach. Sager Decl. ¶ 22.

requests for CDER documents represents a significant increase in such requests beginning in 2004, and has resulted in a corresponding increase in the allocation of DIDP resources. *Id.*; *see, e.g., Emerson v. CIA*, No. 99-0274, 1999 U.S. Dist. LEXIS 19511, at *3, n.2 (D.D.C. Dec. 15, 1999) (“unusual number of comprehensive Congressional requests” alleged and considered as exceptional circumstances).

4. Compliance with specific legislative enactments has further slowed DIDP’s processing of pending requests

In addition, in light of its responsibilities under EFOIA and consistent with Executive Order 13,392,⁷ DIDP proactively reviews, redacts, and posts on FDA’s website certain drug approval packages, approval letters, and warning letters. *Sager Decl.* ¶ 23. DIDP thereby makes available tens of thousands of pages of documents each year regarding newly approved drugs, regardless of whether a FOIA request has been filed for such documents. *Id.* These proactive disclosure efforts reduce the number of incoming FOIA requests each year and so benefit the public, but consume the same level of staffing resources as if they had been made in response to FOIA requests. *Id.* DIDP reviewed, redacted and posted 1,108 approval letters, 99 approval packages, and 35 warning letters in 2006; in 2007, DIDP reviewed, redacted and posted 1,115 approval letters, 92 approval packages, and 51 warning letters. *Id.*

Further, only two weeks before DIDP received Plaintiff’s FOIA request, President Bush signed into law the Food and Drug Administration Amendments Act of 2007 (“FDAAA”). FDAAA resulted in several new or increased obligations for DIDP: some took effect immediately and others must be implemented over the next six months. *Sager Decl.* ¶ 24. Six

⁷ Federal agencies have been encouraged through various management directives, such as Executive Order 13,392, to increase the dissemination of records to the public without the need for FOIA requests.

DIDP employees have been engaged specifically on projects related to FDAAA's new information disclosure requirements during some or all of the pendency of Plaintiff's FOIA request. Id.

B. FDA Has Made Reasonable Progress in Reducing Its Backlog

In 1996, EFOIA further elucidated the standard for obtaining an Open America stay of proceedings, clarifying the "exceptional circumstances" analysis to *exclude* any "delay that results from a predictable agency workload of requests . . . *unless the agency demonstrates reasonable progress in reducing its backlog*" of pending requests. 5 U.S.C. § 552(a)(6)(C)(ii) (emphasis added). As the supporting declarations demonstrate, FDA and DIDP have made excellent progress in reducing their respective backlogs over the past five years and therefore satisfy § 552(a)(6)(C)(ii)'s test to determine whether "exceptional circumstances" exist.

FDA generally – and DIDP specifically – receives vast numbers of FOIA requests, many of which are complex and labor-intensive. DIDP's current backlog of FOIA requests is approximately 3,420. Sager Decl. ¶ 26. The DIDP backlog is attributable to several factors, including: responding to pending complex FOIA requests; a stream of incoming FOIA requests at the rate of approximately 346 per month (from 2003 through 2007); responding to numerous third party subpoenas and discovery requests; responding to Congressional requests for documents; diversion of resources to make thousands of documents publicly available on FDA's website (as part of the agency's compliance with Executive Order 13,392 and EFOIA); responding to new legislative imperatives (e.g., FDAAA); and insufficient resources. This workload results in processing delays, as in this case. Sager Decl. ¶ 25.

DIDP recognizes its tremendous workload and, since 2001, aggressively has taken steps

to reduce the backlog of FOIA requests. These steps have included: (1) implementing new information technology systems; (2) increasing personnel resources; and (3) employing strategies to reduce the volume of incoming FOIA requests. DIDP's activities are described in the accompanying Declaration of Nancy Sager at ¶ 27. Agency declarations "provide a critical insight into" the adequacy of an agency's processes and progress in addressing FOIA requests "and are often determinative." Elec. Privacy Info. Ctr. v. U.S. Dep't of Justice, 2005 U.S. Dist LEXIS 18876, at *11 (D.D.C. Aug. 31, 2005).

To illustrate DIDP's efforts, CDER DIDP has increased its staff from 18 members in 2002 to a current staff of 28 full-time employees and 2 full-time contractors.⁸ Sager Decl. ¶ 27C. DIDP simultaneously implemented new electronic filing systems; internal organizational changes; and public education and outreach efforts to streamline requests. Sager Decl. ¶ 27. DIDP currently plans to hire approximately six more full-time employees in the near future. Sager Decl. ¶ 27C. These activities clearly demonstrate DIDP's efforts to meet its obligations under FOIA.

DIDP's efforts have yielded positive results. DIDP received 5,310 FOIA requests in 2003; 5,156 requests in 2004; 4,050 requests in 2005; 3,335 requests in 2006; and 2,888 requests in 2007. Sager Decl. ¶ 16. Yet, even while training new employees to full productivity, DIDP *processed* approximately 4,340 requests in 2003; 6,800 requests in 2004; 4,876 requests in 2005; 3,907 requests in 2006; and approximately 3,498 requests in 2007. Sager Decl. ¶ 20. Since 2004, therefore, DIDP has processed more than the number of incoming FOIA requests each

⁸ The Division consists of one Director, one special assistant, three team leaders, eleven regulatory counselors, four consumer safety officers, five paralegals, and three project specialists. Sager Decl. ¶ 6.

year. With this rate of processing, DIDP successfully reduced its backlog from an August 2003 high of 6,783, to approximately 3,420 requests as of January 31, 2008 – a reduction of approximately fifty percent (50%) in about five years. Sager Decl. ¶ 26. See Ctr. for Pub. Integrity v. U.S. Dep’t of State, No. 05-2313, 2006 U.S. Dist. 22281 (D.D.C. Apr. 24, 2006) (court determined reasonable progress made based on five-year period). Previously, courts have found FDA's history of reductions in its FOIA backlog and its addition of personnel and resources to satisfy the “reasonable progress” requirement. Appleton, 254 F. Supp. 2d at 10-11 (finding FDA demonstrated reasonable progress in reducing FOIA backlog during 1998-2001 and that year-to-year reductions need not be uniform); Bower, 2004 U.S. Dist. LEXIS 18369, at *7-8 (accepting FDA’s efforts to reduce its backlog).⁹

C. DIDP’s Resources are Inadequate to Meet its FOIA Burden

DIDP has struggled to increase its resources by expanding its full-time staff from 18 to 28 employees during the last five years. See supra at p. 16. Even assuming immediate proficiency for each new employee whom DIDP hired from 2003-2007,¹⁰ the average monthly volume of DIDP’s FOIA requests would require each staff member fully to complete the processing of between three and four FOIA requests per week simply to maintain pace. The complexity of many FOIA requests, intervening and superceding requests for information (due to litigation or Congressional inquiry), and DIDP’s obligation to reduce its backlog of FOIA

⁹But see Bloomberg L.P. v. FDA and Dep’t Health & Human Servs., 500 F. Supp. 2d 371 (S.D.N.Y. 2007); Weinberg v. Von Eschenbach, Civil Case No. 07-1819 (FSH) (D.N.J. October 10, 2007). The Sager declaration, however, addresses the concerns raised by these courts.

¹⁰ Due to the complexity and scientific/technical nature of the work involved in processing FOIA requests for CDER documents, the average new DIDP staff member (whether an employee or contractor) reaches full productivity only after 1-2 years. Sager Decl. ¶ 27C .

requests, render DIDP's resources grossly inadequate to meet FOIA's twenty-day production schedule for new requests.

II. FDA Exercises Good Faith and Due Diligence in Processing FOIA Requests with Minimum Delay

To obtain an Open America stay, FDA also must show good faith effort and the exercise of due diligence in processing FOIA requests. Recognizing federal agencies' legitimate difficulties in meeting high volumes of FOIA requests, and their need to manage thousands of requesters' competing demands, Open America elaborated on FOIA's safe harbor for beleaguered agencies: "The good faith effort and due diligence of the agency to comply with all lawful demands under the Freedom of Information Act in as short a time as is possible by *assigning all requests on a first-in, first-out basis, except those where exceptional need or urgency is shown, is compliance with the Act.*" Open America, 547 F.2d at 616 (emphasis added). Subsequent cases also have affirmed that the system of handling FOIA requests on a "first-in/first-out" basis is a sufficient showing of due diligence. *E.g., Appleton*, 254 F. Supp. 2d at 10 (granting FDA a stay based, in part, upon FDA's "demonstrated good-faith efforts and due diligence in processing plaintiff's request on a first-in, first-out basis"); Edmond, 959 F.Supp. at 3; Jimenez, 938 F.Supp. at 31. DIDP, as a general practice, processes FOIA requests on a two-track, first-in/first-out basis. Sager Decl. ¶¶ 8-14. DIDP—and FDA—therefore meet this factor for an Open America stay.

In addition to exercising due diligence in its handling of FOIA requests in general, FDA demonstrated good faith and due diligence in processing Plaintiff's request within the limits of its first-in/first-out process, including prompt forwarding of the request to component offices and the partial release of responsive documents as they were located. CBER responded to Plaintiff

with documents on November 6, 2007. Complaint ¶ 4. OC searched and then responded, through DFOI, to Plaintiff on January 24, 2008. Sadler Decl. ¶ 13; Sadler Decl. Exhibit 3. DIDP twice has called Plaintiff regarding the status of the FOIA request. Sager Decl. ¶ 29. See, e.g., Appleton, 254 F. Supp. 2d at 10 (agency logged and acknowledged plaintiff's request, then promptly transmitted readily available records).

CONCLUSION

FOIA's exception at 5 U.S.C. § 552(a)(6)(C) permits courts to grant stays of proceedings to allow federal agencies additional time to respond to FOIA requests. An agency is entitled to a stay if it demonstrates: (1) exceptional circumstances; and (2) due diligence in responding to the request. Additionally, if an agency's high volume of FOIA requests is predictable, to show "exceptional circumstances" the agency must demonstrate reasonable progress in reducing any FOIA request backlog.

In this case, two relevant FDA components have responded to Plaintiff's FOIA request. The remaining Agency component with responsive documents, CDER, is struggling to overcome an enormous volume of FOIA requests, Congressional requests, and litigation-related document requests, among other duties. CDER DIDP processes FOIA requests on a first-in/first-out basis in an effort to treat all requesters fairly, in good faith and with due diligence, and to respond to FOIA requests with minimum delay. As part of this effort DIDP uses a two-track system; responds simultaneously when possible to requests for the same, or substantially similar documents; has reorganized its work processes and implemented new information technology systems; and, over the course of the last five years, has increased its staff. These efforts have resulted in a fifty per cent (50%) decrease in CDER's FOIA request backlog from August 2003

to January 2008.

Therefore, for the foregoing reasons, FDA respectfully requests that further proceedings in this matter be stayed, pursuant to 5 U.S.C. § 552(a)(6)(C), for twenty months to allow FDA to process Plaintiff's request on a first-in/first-out basis. In the interim, FDA will submit status reports as determined by the Court.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on February 18, 2008, I electronically filed the foregoing Motion to Stay Proceedings with the Clerk of the Court using the CM/ECF system, which will send notification to Kerry M. Donahue.

s/John J. Stark _____
John J. Stark
Assistant United States Attorney