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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

CHARLES SEIFE, Plaintiff, *vs*. **UNITED STATES FOOD AND DRUG ADMINISTRATION,** Defendant.	Case No. 1:15-cv-5487 **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF** Freedom of Information Act Administrative Procedure Act

Plaintiff, Charles Seife, ("Plaintiff" or "Seife"), alleges as follows:

INTRODUCTION

1. This action is premised upon, and consequent to, violations of both the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 *et. seq.*, and the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 *et. seq*. It challenges the unlawful failure of the Defendant, the United States Food and Drug Administration ("FDA"), to respond to Plaintiff's five FOIA requests and appeals within the time and in the manner required by FOIA. Although the FDA has disclosed certain documents responsive to Plaintiff's requests, it has unnecessarily, unreasonably, and unlawfully failed to provide final decisions regarding additional records responsive to Seife's requests. Moreover, FDA is unlawfully withholding information responsive to Plaintiff's FOIA requests

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that does not fall within the scope of FOIA's exemptions to mandatory disclosure.

2. The purpose of the FOIA is "to establish a general philosophy of full agency disclosure unless information is exempted under clearly delineated statutory language." S.Rep. No. 813, 89th Cong., 1st Sess., 3 (1965). The FOIA therefore requires federal agencies to disclose records to any person upon request unless the information falls within one of nine narrow disclosure exemptions listed in the Act. *See* 5 U.S.C. § 552(a)(3)(A), (b). Except in unusual circumstances, federal agencies generally must determine within twenty business days whether requested records are exempt from withholding and, if they are not, the agency must "promptly disclose" the records to the requester. 5 U.S.C. §§ 552(a)(6)(A)(i); *id.* at (a)(3)(A), (a)(6)(C)(i).

3. On May 5, 2014, December 9, 2015, and February 9, 2015, Plaintiff Seife submitted a total of five Freedom of Information Act requests to the FDA. The FOIA requests sought information relating to the FDA's role in the regulation and approval of drugs and in particular, records pertaining to FDA's handling of instances of fraud, misconduct and subterfuge by scientists and corporations seeking approval for drugs and medical devices, as well as the Agency's attempts to manipulate the flow of information about the Agency's actions to the public and to the press.

4. The FDA violated the FOIA's provisions in processing Plaintiff's information requests. First, the Agency has failed to release information that does not properly fall within the ambit of any of FOIA's disclosure exemptions. Second, FDA failed to issue a final determination on Plaintiff's administrative requests and appeals within the time allowed by the Act. Third, FDA has repeatedly failed to provide Plaintiff with estimated completion dates for his information requests as required by FOIA.

5. Plaintiff recognizes the realities of FDA's workload and has been more than willing to give the Agency additional time to make the required determinations and to disclose requested

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records in this and many other matters. But in this case FDA has missed almost every applicable deadline while showing little sign that it will ever actually disclose the requested records to Plaintiff on a timeline that will allow him to use them to provide meaningful public oversight of the Agency's handling of fraud, misconduct and subterfuge in the drug and medical device approval process.

6. Defendant is unlawfully withholding public disclosure of information sought by Plaintiff, information to which he is entitled and for which no valid disclosure exemption applies. Defendant violated the statutory mandates and deadlines imposed by FOIA through its failure to provide final determinations resolving Plaintiff's FOIA requests and appeals within the time and manner required by law. Additionally, Defendant has unlawfully withheld certain information responsive to Plaintiff's requests by applying FOIA's disclosure exemptions in an overly broad manner not supported by the Act's clear language. Accordingly, Plaintiff seeks declaratory relief establishing that Defendant has violated the FOIA and APA. Plaintiff also seeks injunctive relief directing Defendant to promptly provide Plaintiff with the requested material.

JURISDICTION, VENUE AND BASIS FOR RELIEF

7. This Court has jurisdiction over this matter pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331 because this action arises under the FOIA, the APA, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq*.

8. Venue properly vests in this Court pursuant to 5 U.S.C. § 552(a)(4)(B), which provides venue for FOIA cases in this district because the Plaintiff resides within this judicial district. Assignment is proper in this district for the same reasons.

9. Declaratory relief is appropriate under 28 U.S.C. § 2201.

10. Injunctive relief is appropriate under 28 U.S.C. § 2202 and 5 U.S.C. § 552(a)(4)(B).

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PARTIES

11. Plaintiff, Charles Seife, is a professor of journalism at New York University as well as an award-winning reporter and author who is both widely published and read. In addition to having published six critically acclaimed books on mathematical and scientific subjects, his journalism has appeared in numerous newspapers and magazines, including *The New York Times*, *The Washington Post*, *The Philadelphia Inquirer*, *Science*, *The Los Angeles Times*, *The Economist*, *Smithsonian*, *Discover*, *Scientific American*, and many other publications. He has performed a number of investigations of how federal agencies handle — and mishandle — instances of scientific misconduct in clinical trials. These investigations have been published by *Scientific American*, *ProPublica* and *Slate*, and have led to a peer-reviewed publication in *JAMA Internal Medicine.* Seife is the requester of the records which Defendant is now withholding. He has requested this information because he is developing several stories about a number of FDA policies and actions that are potentially injurious to the public health and may undermine the public trust in the Agency. Specifically, he has discovered that the Agency is aware of scientific fraud undermining the integrity of clinical trials that are being used to establish the safety and efficacy of hundreds of drugs on the market in the United States. He has established not only that in many cases, FDA has actively decided not to disclose this fraud to the public, but also that the agency has been willing to let pharmaceutical manufacturers include information on drug labels that the agency has itself deemed "unreliable" because of fraud. The information plaintiff requests is intended to allow the public to analyze the extent to which the FDA has failed to disclose research misconduct that has tainted the scientific literature; to notify the public and scientific community about the nature and extent of these cases of fraud and reveal which drugs' safety and efficacy data has been undermined (and to what degree); to examine FDA practices with regard to discoveries of substantial research misconduct, especially in light of several large fraud cases which

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all follow a common pattern of non-disclosure; and to examine FDA's behavior with regard to transparency with the public, with the scientific community, and with the press. There exists substantial public interest in this information, and the Plaintiff intends to write one or more publications based upon the contents of these documents. The records sought in this action are requested in support of these efforts.

12. Defendant United States Food and Drug Administration, is an agency of the executive branch of the United States government, it is in possession and control of the records sought by Plaintiff, and as such, it is subject to the FOIA pursuant to 5 U.S.C. § 552(f).

STATUTORY BACKGROUND

13. The FOIA imposes strict and rigorous deadlines on federal agencies. The Act requires a federal agency that receives a FOIA request to determine whether the requested records are exempt from disclosure under 5 U.S.C. § 552(b) and to communicate that determination to the requester within twenty business days. 5 U.S.C. § 552(a)(6)(A)(i). If the agency determines the requested records are exempt from public disclosure, the agency must also communicate to the requester that they have a right to appeal that determination. *Id.* If the agency determines the records are not exempt from public disclosure, the agency is required to make the requested records "promptly available" to the requester. 5 U.S.C. § 552(a)(3)(A), (a)(6)(C)(i).

14. Congress has set forth the circumstances in which federal agencies may obtain more time to make the determination required by 5 U.S.C. § 552(a)(6)(A)(i). In two very limited circumstances the agency may toll the twenty business-day deadline for making that determination. 5 U.S.C. § 552(a)(6)(A)(ii) (providing for up to a ten-day tolling period to allow an agency to seek information from a requester). Additionally, the agency may extend the twenty business-day deadline for making that determination for an additional ten business days by providing a written notice to the requester that sets forth the "unusual circumstances" that justify the deadline exten-

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sion and the date on which the agency expects to make the determination. 5 U.S.C. § 552(a)(6)–(B)(ii). The statute includes a specific definition of the term "unusual circumstances." 5 U.S.C. § 552(a)(6)(B)(iii). And when the agency notifies a requester of unusual circumstances and the need for additional time, the agency's written notification "shall provide the person an opportunity to limit the scope of the request so that it may be processed within that time limit or an opportunity to arrange with the agency an alternative time frame for processing the request or a modified request." 5 U.S.C. § 552(a)(6)(B)(ii). Moreover, an agency asserting that unusual circumstances prevent its compliance with FOIA's deadlines "shall make available its FOIA Public Liaison, who shall assist in the resolution of any disputes between the requester and the agency." *Id*.

15. Unless an agency subject to the FOIA establishes a different timeline for disclosing responsive records by providing sufficient written notice of unusual circumstances, the FOIA's mandate to make public records "promptly available" to a requester requires federal agencies to provide responsive records to a requester within or shortly after the twenty-day timeframe set forth in 5 U.S.C. § 552(a)(6)(A)(i).

16. A U.S. District Court has jurisdiction "to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant." 5 U.S.C. § 552(a)(4)(B). If the government can show that "exceptional circumstances" exist and that the agency is exercising due diligence in responding to the request, the court may retain jurisdiction and allow the agency additional time to complete its review of the records. 5 U.S.C. § 552(a)(6)(C)(i). Notably, the term "exceptional circumstances" does *not* include a delay that results from a predictable agency workload of FOIA requests, unless the agency demonstrates reasonable progress in reducing its backlog of pending requests. 5 U.S.C. § 552(a)(6)-(C)(ii).

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17. Agency action under the FOIA is also subject to judicial review under the APA. *Oregon Natural Desert Ass'n.. v. Gutierrez*, 409 F.Supp.2d 1237, 1248 (D.Or. 2006) (finding that violation of the FOIA's decision deadline constitutes APA violation for an agency action that is not in accordance with the law), *affirmed in part, reversed on other grounds*, *Oregon Natural Desert Ass'n v. Locke*, 572 F.3d 610 (9th Cir. 2009). Under the judicial review provisions of the APA, district courts are authorized to compel agency action unlawfully withheld or unreasonably delayed. 5 U.S.C. § 706(1). District courts must also set aside any agency action found to be arbitrary, capricious, an abuse of discretion, not in accordance with law, or made without observation of required procedures. 5 U.S.C. § 706(2).

STATEMENT OF OPERATIVE FACTS
Regarding FOIA Request 2014-3702

18. Via FDA's internet portal, on May 5, 2014, Plaintiff requested documents relating to FDA's interactions with the press — particularly with respect to so-called "embargoed" press briefings in which select members of the press would get copies of the recommendations prior to their public release provided that the recipients agreed not to share the information to outside parties prior to the expiration of the embargo.

19. The FDA has on multiple occasions — and in violation of the agency's stated policy — offered advance information to journalists on the condition that journalists not discuss the matter with third parties before the expiration of the embargo. This practice is considered unethical by many journalism experts, as it is a case where, in the words of *New York Times* public editor Margaret Sullivan, "... the government [is] telling journalists to whom they can and can't talk.... [t]his practice ought to be stomped out."

20. Plaintiff wishes to illuminate the changing policies of the FDA's press office, and why it is willing to violate its own guidelines with respect to embargoed information. To this end, Plaintiff submitted a FOIA request for a variety of documents regarding FDA's and HHS' policies

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regarding news embargoes, about restrictions put on members of the press who agreed to get information in advance, about which journalists would and would not be allowed to participate in embargoed news briefings, and the like.

21. Via e-mail dated May 23, 2014, the agency asked for a telephone call to clarify Plaintiff's intent with the request. Plaintiff agreed, and met with the agency over the telephone on May 28, 2014.

22. Via e-mail dated December 9, 2014, the agency notified Plaintiff that "... responsive records are currently with the FOIA office and going through the redaction process."

23. Via e-mail dated February 17, 2015, Plaintiff inquired regarding the status of this request, noting that he hadn't heard anything since December.

24. Via e-mail dated February 17, 2015, the agency notified Plaintiff that it was "...waiting on some additional information from my office and may be from another office as well since some of the responsive records were of mixed ownership."

25. Via e-mail dated March 4, 2015, the agency notified Plaintiff that "... the FOIA office was finalizing the responsive material so you should be receiving a response to your FOIA soon."

26. Via e-mail dated March 23, 2015, the agency provided what it termed a "partial response" to the request. This partial response consisted of a PDF file containing 18 pages of e-mails. Large portions of those e-mails were redacted pursuant to Exemption 5.

27. Via mail dated March 29, 2015, the agency sent a second "partial response" to the request. The second partial response consisted of 78 pages of e-mails. Large portions of those e-mails were redacted, also primarily pursuant to Exemption 5 but also invoking Exemption 6 to redact a single passage. Other portions of those e-mails were redacted as "non responsive" without reference to a FOIA exemption, even though the request was for e-mails or other documents

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that mentioned various subjects; the entire e-mail, by definition, would either be responsive or not responsive.

28. Via e-mail dated July 7, 2015, Plaintiff again contacted FDA to inquire as to the status of his request and to warn that litigation might soon become necessary. Via e-mail dated July 10, 2015 and July 13, 2015, FDA provided a third partial response and a fourth partial response. Like the first and second partial responses, these responses were heavily redacted, mostly pursuant to exemption 5, but, in places, pursuant to exemption 6 and also as "non responsive." The agency noted that Plaintiff's "request remains open and [the agency] continues to process [his] request for records regarding other embargos."

29. In addition to redacting elements of the documents as "non responsive" despite the fact that the entire documents are either responsive or non responsive, the Agency's search is inadequate and redactions are inappropriate in a number of ways: "drafts" of key documents — including a communications plan, press releases, scripts, talking points, and "policy" (presumably regarding press embargoes), there are no final documents provided; names of people are redacted pursuant to Exemption 5 to prevent identification, not to protect the deliberative process; documents that explain rationales for strategies that were apparently implemented were also redacted, as were documents regarding delegations of tasks, updates about ongoing developments, and other factual matters; the agency redacted some communications from outsiders pursuant to Exemption 5 despite clear indications that the outsiders were not acting as consultants; and for numerous other reasons.

30. The FOIA requires an agency to issue a final determination resolving a FOIA request within twenty business days from the date of its receipt. 5 U.S.C. § 552(a)(6)(A)(i).

31. Defendant failed to respond to the information request within 20 business days from receipt of Plaintiff's May 5, 2014 FOIA request as required by 5 U.S.C. § 552(a)(6)(A)(i).

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32. Defendant failed to provide a written notice to the Plaintiffs asserting that "unusual circumstances" prevented it from compliance with FOIA's decision deadline and providing the date on which the Agency expected to make the determination. 5 U.S.C. § 552(a)(6)(B)(ii).

33. At the very latest, based on the May 5, 2014 date of Plaintiff's FOIA request (and accounting for the Memorial Day Holiday), the deadline for issuing a final determination of Plaintiff's FOIA request elapsed on June 3, 2014.

34. None of FOIA's nine exemptions to mandatory disclosure apply to the information currently being withheld by the FDA that is responsive to Plaintiff's FOIA request.

35. As of the date this action was filed, the deadline for the FDA to issue a final determination on Plaintiff's pending FOIA request has passed.

36. As of the date this action was filed, the FDA has not provided a final determination on Plaintiff's FOIA request pending with the Agency.

37. As of the date this action was filed, the FDA has not informed Plaintiff with an estimated completion date for FOIA request currently pending with the Agency.

38. Because the Agency has not issued a final response to his FOIA request, Plaintiff has not filed an administrative appeal of any determination, and therefore has constructively exhausted all administrative remedies required by FOIA. 5 U.S.C. §§ 552(a)(6)(A), (a)(6)(C).

39. Plaintiff has been required to expend costs and to obtain the services of a law firm to prosecute this claim.

40. Plaintiff's claims presented herein are not insubstantial within the meaning of 5 U.S.C. § 552(a)(4)(E)(ii)(II).

Regarding FOIA Request 2015-1069

41. By e-mail dated December 9, 2014, Plaintiff requested access to unredacted copies of all Warning Letters, Notices of Initiation of Disqualification Proceedings and Opportunity to Ex-

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plain (NIDPOEs), and Notices of Opportunity for a Hearing (NOOHs), dated after January 1, 1998, issued to (or regarding) clinical investigators. These documents are typically issued by FDA after agency inspectors find particularly grave and objectionable conditions at a site involved in a clinical trial of a drug or a medical device.

42. Many such Warning Letters, NIDPOEs, and NOOHs are published on FDA's website, but with redactions pursuant to FOIA Exemption 4 and FOIA Exemption 6. The vast majority of redactions pursuant to FOIA Exemption 4 are names and numbers of clinical trial protocols, the names of the drugs and/or devices involved in those trials, and the identity of the trial sponsor. In general, these items of information should not be withheld under Exemption 4. Many of the redactions pursuant to FOIA Exemption 6 appear to be subject numbers, which are de-identified and therefore do not present any risk to the subject's privacy and should not be withheld under Exemption 6.

43. During a telephone conversation on January 14, 2015 requested by Darshini Satchi, a FOIA officer employed by defendant FDA, Satchi stated that the request — which likely involves gathering and redacting perhaps 500 documents, each of which is roughly three pages long — was enormous. Satchi further stated that the agency could at most "re-review a single letter or two per month." She then stated that unless Plaintiff modified the request to a "reasonable size" of one or two documents, it would take many years to process.

44. At the projected rate of one or two documents per month, fulfilling Plaintiff's request would take more than 20 years, which might be appropriate if Plaintiff's request were one of the most complex and difficult FOIA requests ever received by any executive-branch agency.

45. By e-mail on January 14, 2015 to Darshini Satchi, Plaintiff requested clarification about why it would take so long to gather and process the requested documents. Plaintiff noted that that the documents were presumably located in a small number of offices all sited at FDA headquar-

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ters. Plaintiff also noted that the FDA FOIA office had already processed many, if not most of the documents already, leaving only a few redactions per document that needed to be re-reviewed. Further, many of the documents were readily findable via the FDA website. All of these facts would seem to imply that the request should be processed extremely rapidly.

46. By e-mail on January 17, Darshini Satchi responded to Plaintiff's query. The e-mail stated that the request would be in the complex queue, as the agency would have to "review many letters over the past decade or so..." and that the "exemption 4 issue is no small issue" because it would require a "... review [of] protocols to see if whether they relate to a currently approved product."

47. By e-mail on January 19, Plaintiff responded to Ms. Satchi's e-mail request, attempting to get clarification about whether the agency would need years to process his request once it came to the top of the complex queue, and to get further information about the nature of the exemption 4 withholdings.

48. By e-mail dated March 11, 2015, Plaintiff again requested an estimated completion date for processing Plaintiff's request.

49. By e-mail dated March 11, 2015, Ms. Satchi stated that Plaintiff's request was being handled by several offices at FDA. She further stated that the wait time at CDER would be "approximately 24 months."

50. By e-mail dated March 18, 2015, the agency notified Plaintiff that the wait time at CDRH — another office in the agency — "will be approximately 12 months before it comes up for processing in the queue."

51. By e-mail dated April 10, 2015, Plaintiff requested an estimated completion date for the portion of the request that had been sent to CBER — a third office in the agency likely to be handling the request.

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52. By telephone, on April 13, 2015, the agency notified Plaintiff that the wait time at CBER was "hard to estimate, as it is a little dynamic... it is on the order of months, and could be like a year or more before it's up in the queue."

53. The FOIA requires an agency to issue a final determination resolving a FOIA request within twenty business days from the date of its receipt. 5 U.S.C. § 552(a)(6)(A)(i).

54. Defendant failed to respond to the information request within 20 business days from receipt of Plaintiff's December 9, 2014, FOIA request as required by 5 U.S.C. § 552(a)(6)(A)(i).

55. Defendant failed to provide a written notice to the Plaintiffs asserting that "unusual circumstances" prevented it from compliance with FOIA's decision deadline and providing the date on which the Agency expected to make the determination. 5 U.S.C. § 552(a)(6)(B)(ii).

56. At the very latest, based on the December 9, 2014 date of Plaintiff's FOIA request (and accounting for the Christmas and New Years Holidays), the deadline for issuing a final determination of Plaintiff's FOIA request elapsed no later than January 9, 2015.

57. None of FOIA's nine exemptions to mandatory disclosure apply to the information currently being withheld by the FDA that is responsive to Plaintiff's FOIA request.

58. As of the date this action was filed, the deadline for the FDA to issue a final determination on Plaintiff's pending FOIA request has passed.

59. As of the date this action was filed, the FDA has not provided a final determination on Plaintiff's FOIA request pending with the Agency.

60. As of the date this action was filed, the FDA has not informed Plaintiff with an estimated completion date for FOIA request currently pending with the Agency.

61. Because the Agency has not issued a final response to his FOIA request, Plaintiff has not filed an administrative appeal of any determination, and therefore has constructively exhausted all administrative remedies required by FOIA. 5 U.S.C. §§ 552(a)(6)(A), (a)(6)(C).

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62. Plaintiff has been required to expend costs and to obtain the services of a law firm to prosecute this claim.

63. Plaintiff's claims presented herein are not insubstantial within the meaning of 5 U.S.C. § 552(a)(4)(E)(ii)(II).

Regarding FOIA Request 2015-1142

64. By fax dated February 9, 2015, Plaintiff requested a set of documents regarding the agency's handling of a major case of fraud. In late 2014, the French equivalent of the FDA — the ANSM (French National Agency for Medicines and Health Products Safety) — found fraud at a research firm known as GVK Biosciences; as a result, in early 2015, the European Medicines Association (EMA) recommended pulling some 700 drugs off the European market. FDA has identified some 40 drugs on the US market that were affected by the GVK fraud. It is unclear what steps FDA has taken to ensure that those affected drugs are safe and effective given that the scientific data on those drugs had been proven to be unreliable.

65. The documents that Plaintiff requested were intended to shed light onto the nature of the GVK fraud and how the FDA was handling (or failing to handle) a major case of research mis-conduct that undermines confidence in the safety, efficacy, and bioequivalence of drugs on the market. Specifically, Plaintiff requested (a) various FDA-generated documents regarding any inspection of GVK Biosciences' facilities dated on or after the beginning of September, 2014; (b) communications between the FDA and EMA and/or ANSM regarding GVK Biosciences; (c) documents in which the FDA identifies one or more of the 40 applications that contain GVK clinical study data from 2007 to March 2012; and (d) documents describing FDA's decision on how to handle the problem presented by the allegations regarding GVK Biosciences.

66. By letter dated February 10, 2015, FDA acknowledged receipt of the request.

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67. By e-mail dated February 24, 2015, FDA notified me that Plaintiff's request was going to be placed in the complex queue, and would thus take 18 to 24 months to process. However, the agency gave Plaintiff the option to accept a copy of a previously-released document (a "Form 483") regarding an inspection of GVK Biosciences in lieu of completing the request.

68. By e-mail dated February 24, 2015, Plaintiff notified FDA that the form 483 was of interest, and that it might allow Plaintiff to modify his request to reduce the agency's burden, and asked for FDA to send it.

69. By e-mail dated February 24, 2015, FDA notified Plaintiff that sending over the Form 483 would result in the request's being considered completed.

70. By e-mail dated March 2, 2015, Plaintiff declined FDA's offer to receive a Form 483 in lieu of completing Plaintiff's request.

71. By e-mail dated March 11, 2015, Plaintiff requested an estimated completion date.

72. By e-mail dated March 12, 2015, FDA stated that, as Plaintiff did not amend his request, completing it "may now take up to 24 months."

73. The FOIA requires an agency to issue a final determination resolving a FOIA request within twenty business days from the date of its receipt. 5 U.S.C. § 552(a)(6)(A)(i).

74. Defendant failed to respond to the information request within 20 business days from receipt of Plaintiff's February 9, 2015, FOIA request as required by 5 U.S.C. § 552(a)(6)(A)(i).

75. Defendant failed to provide a written notice to the Plaintiffs asserting that "unusual circumstances" prevented it from compliance with FOIA's decision deadline and providing the date on which the Agency expected to make the determination. 5 U.S.C. § 552(a)(6)(B)(ii).

76. At the very latest, based on the February 9, 2015 date of Plaintiff's FOIA request, the deadline for issuing a final determination of Plaintiff's FOIA request was March 9, 2015.

77. None of FOIA's nine exemptions to mandatory disclosure apply to the information cur-

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rently being withheld by the FDA that is responsive to Plaintiff's FOIA request.

78. As of the date this action was filed, the deadline for the FDA to issue a final determination on Plaintiff's pending FOIA request has passed.

79. As of the date this action was filed, the FDA has not provided a final determination on Plaintiff's FOIA request pending with the Agency.

80. As of the date this action was filed, the FDA has not informed Plaintiff with an estimated completion date for FOIA request currently pending with the Agency.

81. Because the Agency has not issued a final response to his FOIA request, Plaintiff has not filed an administrative appeal of any determination, and therefore has constructively exhausted all administrative remedies required by FOIA. 5 U.S.C. §§ 552(a)(6)(A), (a)(6)(C).

82. Plaintiff has been required to expend costs and to obtain the services of a law firm to prosecute this claim.

83. Plaintiff's claims presented herein are not insubstantial within the meaning of 5 U.S.C. § 552(a)(4)(E)(ii)(II).

Regarding FOIA Request 2015-1143

84. By fax dated February 9, 2015, Plaintiff requested a different set of documents related to a notorious case of fraud involving the Cetero corporation, which paralleled, in many ways, the more recent fraud at GVK Biosciences. Cetero, like GVK, was an organization that performed research for a large number of pharmaceutical firms. Cetero, like GVK, had been faking tests that were submitted to the FDA as evidence of a number of drugs' safety, efficacy, and/or biologic equivalence to existing approved pharmaceuticals. By knowledge and belief, 81 drugs on the US market were approved on the basis of tests that the FDA later deemed to be "unreliable" because of the fraud at Cetero. In 2011, FDA required the marketers of those 81 drugs to submit new data within six months, putatively so that the agency could re-review the drugs. As of early

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2015, those re-reviews had not been completed. Also as of early 2015, the agency has not revealed which drugs' approvals were dependent on fraudulent data, whether marketers had (or had not) resubmitted information as required, and which re-reviews had or had not been completed.

85. The documents that Plaintiff requested were intended to shed light onto the nature of the Cetero fraud and how the FDA was handling (or failing to handle) a major case of research misconduct that undermines confidence in the safety, efficacy, and bioequivalence of drugs on the market.

86. Like request No. 2015-1144, *infra*, this request was intended to illuminate FDA's response to the undermining of safety, effectiveness, and bioequivalence data of drugs on the US market by the Cetero fraud. However, its scope was extremely narrow so as to ensure that it would be processed quickly by the agency.

87. Specifically, Plaintiff requested a single letter (which included two appendices, clearly marked "Attachment A" and "Attachment B") that was sent by Cetero corporation's Chief Executive Officer, Roger Hayes to the FDA on July 26, 2011.

88. By letter dated February 10, 2015, FDA acknowledged receipt of the request and assigned it the reference number 2015-1143.

89. By letter dated February 11, 2015, FDA — specifically, a FOIA officer with the Center for Drug Evaluation and Research ("CDER") — provided a "partial response" to Plaintiff's request. The agency provided the body of Hayes' letter (17 pages), but failed to provide Attachment A or Attachment B. The agency's note stated that "... other staff within the FDA will be responding to the remaining portion of your request."

90. By e-mail dated March 2, 2015, Plaintiff requested clarification of FDA, asking why the attachments were not included in the response, asking which office — if not CDER — was han-

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dling the rest of the response, and requesting an estimated completion date for the remainder of the request. FDA did not provide an explanation or estimated completion date.

91. By e-mail dated April 10, 2015, Plaintiff asked again for clarification and an estimated completion date for the remainder of the request.

92. By letter dated April 14, 2015, FDA denied the remainder of the request, citing FOIA Exemption (b)(4). The volume of the denied material was 41 pages, and presumably included Attachment A and Attachment B.

93. Via e-mail and letter dated April 27, 2015, Plaintiff timely appealed the agency's decision. The reasons for the appeal were: (a) that the agency erred in withholding the document pursuant to Exemption 4, as the records requested do not constitute trade secrets or commercially confidential information; (b) that the agency erred in withholding the document in entirety rather than releasing the reasonably segregable portions of the records after the exempt portions have been redacted; (c) that the agency erred in not providing information sufficiently specific to allow a reasoned judgment whether the material is actually exempt under FOIA; and (d) that the agency erred in not performing an adequate search for documents. Plaintiff also requested an estimated completion date in the appeal.

94. By e-mail dated April 29, 2015, the Department of Health and Human Services acknowledged receipt of the appeal.

95. By e-mail dated May 15, 2015, Plaintiff again reiterated his request — also voiced in the appeal letter — for an estimated completion date. Neither Department of Health and Human Services or the Food and Drug Administration responded to this e-mail.

96. By e-mail dated May 28, 2015, Plaintiff once again noted HHS' violation of 5 USC 552 and asked once again for an estimated completion date. Department of Health and Human Serv-

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ices stated that due to the HHS' "long complicated process" for handling appeals, "[w]e expect to process your appeal within the next six months. "

97. Defendant failed to respond to the information request within 20 business days from receipt of Plaintiff's February 9, 2015, FOIA request as required by 5 U.S.C. § 552(a)(6)(A)(i).

98. Defendant failed to provide a written notice to the Plaintiffs asserting that "unusual circumstances" prevented it from compliance with FOIA's decision deadline and providing the date on which the Agency expected to make the determination. 5 U.S.C. § 552(a)(6)(B)(ii).

99. At the very latest, based on the February 9, 2015 date of Plaintiff's FOIA request, the deadline for issuing a final determination of Plaintiff's FOIA request was March 9, 2015.

100. Defendant's April 14, 2015 final decision on this FOIA request therefore violated FOIA's statutory deadline.

101. The FOIA requires an agency to issue a final determination resolving a FOIA appeal within twenty business days from the date of its receipt. 5 U.S.C. § 552(a)(6)(A)(ii).

102. Defendant failed to make a final determination within 20 business days from receipt of Plaintiff's April 27, 2015, FOIA appeal as required by 5 U.S.C. § 552(a)(6)(A)(ii).

103. Defendant failed to provide a written notice to the Plaintiffs asserting that "unusual circumstances" prevented it from compliance with FOIA's appeal decision deadline and providing the date on which the Agency expected to make the determination. 5 U.S.C. § 552(a)(6)(B)(ii).

104. At the very latest, based on the April 27, 2015 date of Plaintiff's FOIA appeal, the deadline for issuing a final determination of Plaintiff's FOIA appeal was May 25, 2015.

105. None of FOIA's nine exemptions to mandatory disclosure apply to the information currently being withheld by the FDA that is responsive to Plaintiff's FOIA request.

106. As of the date this action was filed, the deadline for the FDA to issue a final determination on Plaintiff's pending FOIA appeal has passed.

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(541) 556-6439

107. As of the date this action was filed, the FDA has not provided a final determination on Plaintiff's FOIA appeal pending with the Agency.

108. As of the date this action was filed, the FDA has not informed Plaintiff with an estimated completion date for FOIA appeal currently pending with the Agency.

109. Plaintiff has fully exhausted all administrative remedies required by FOIA. 5 U.S.C. §§ 552(a)(6)(A), (a)(6)(C).

110. Plaintiff has been required to expend costs and to obtain the services of a law firm to prosecute this claim.

111. Plaintiff's claims presented herein are not insubstantial within the meaning of 5 U.S.C. § 552(a)(4)(E)(ii)(II).

Regarding FOIA Request 2015-1144

112. By fax dated February 9, 2015, Plaintiff submitted a request that sought access to a number of other documents related to FDA's handling of the Cetero fraud. Specifically, he requested (a) communications in which the FDA asked that a drug company provide new data as a result of the Cetero fraud; (b) for each of the firms that provided new data to the FDA as requested, the full communication in which the firm provided that data to the FDA; and (c) copies of FDA's reviews of the repeated bioequivalence studies that it had completed to date.

113. By letter dated February 10, 2015, FDA acknowledged receipt of the request and assigned it the reference number 2015-1144.

114. On March 4, 2015, FDA denied the request in full, citing FOIA Exemption (b)(3) and (b)(4).

115. On March 13, 2015, Plaintiff timely appealed the agency's decision. The reasons for the appeal were: (a) that the agency erred in withholding the document pursuant to Exemption 4, as the records requested do not constitute trade secrets or commercially confidential information;

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(b) that the agency erred in withholding information pursuant to Exemption 3, and that the agency failed to justify such a withholding with an appropriate withholding statute; (c) that the agency erred in withholding the document in entirety rather than releasing the reasonably segregable portions of the records after the exempt portions have been redacted; (d) that the agency erred in not providing information sufficiently specific to allow a reasoned judgment whether the material is actually exempt under FOIA; and (e) that the agency erred in not performing an adequate search for documents.

116. By letter dated March 20, 2015, the Department of Health and Human Services acknowledged receipt of the appeal.

117. By e-mail dated April 10, 2015, Plaintiff noted that the statutory 20-day period for a response had elapsed, and requested an estimated completion date for the agency's response to my appeal.

118. By e-mail dated April 10, 2015, the Department of Health and Human Services stated that due to the HHS' "thorough process" for handling appeals, "[w]e expect to have your appeal complete within the next few months.

119. By e-mail dated April 10, 2015, Plaintiff noted HHS' violation of FOIA and asked again for an estimated completion date, as "within the next few months" was too vague to allow Plaintiff to understand whether the agency would comply with its statutory responsibilities in a timely manner. Neither Department of Health and Human Services or the Food and Drug Administration responded to this e-mail.

120. By e-mail dated May 15, 2015, Plaintiff again noted HHS' violation of 5 USC 552 and asked once again for an estimated completion date. Neither Department of Health and Human Services or the Food and Drug Administration responded to this e-mail.

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121. By e-mail dated May 28, 2015, Plaintiff once again noted HHS' violation of 5 USC 552 and asked once again for an estimated completion date. Department of Health and Human Services stated that due to the HHS' "long complicated process" for handling appeals, "[w]e expect to process your appeal within the next six months. "

122. The FOIA requires an agency to issue a final determination resolving a FOIA appeal within twenty business days from the date of its receipt. 5 U.S.C. § 552(a)(6)(A)(ii).

123. Defendant failed to make a final determination within 20 business days from receipt of Plaintiff's March 13, 2015, FOIA appeal as required by 5 U.S.C. § 552(a)(6)(A)(ii).

124. Defendant failed to provide a written notice to the Plaintiffs asserting that "unusual circumstances" prevented it from compliance with FOIA's appeal decision deadline and providing the date on which the Agency expected to make the determination. 5 U.S.C. § 552(a)(6)(B)(ii).

125. At the very latest, based on the March 13, 2015 date of Plaintiff's FOIA appeal, the deadline for issuing a final determination of Plaintiff's FOIA appeal was April 10, 2015.

126. None of FOIA's nine exemptions to mandatory disclosure apply to the information currently being withheld by the FDA that is responsive to Plaintiff's FOIA request.

127. As of the date this action was filed, the deadline for the FDA to issue a final determination on Plaintiff's pending FOIA appeal has passed.

128. As of the date this action was filed, the FDA has not provided a final determination on Plaintiff's FOIA appeal pending with the Agency.

129. As of the date this action was filed, the FDA has not informed Plaintiff with an estimated completion date for FOIA appeal currently pending with the Agency.

130. Plaintiff has fully exhausted all administrative remedies required by FOIA. 5 U.S.C. §§ 552(a)(6)(A), (a)(6)(C).

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131. Plaintiff has been required to expend costs and to obtain the services of a law firm to prosecute this claim.

132. Plaintiff's claims presented herein are not insubstantial within the meaning of 5 U.S.C. § 552(a)(4)(E)(ii)(II).

CAUSES OF ACTION
COUNT I
VIOLATION OF THE FREEDOM OF INFORMATION ACT:
CONSTRUCTIVE DENIAL/UNLAWFUL WITHHOLDING

133. The allegations made in all preceding paragraphs are realleged and incorporated by reference herein.

134. Plaintiff has a statutory right to the records he seeks, and there is no legal basis for Defendant FDA to assert that any of FOIA's nine disclosure exemptions apply. *See* 5 U.S.C. § 552(b)(l)-(9).

135. Defendant FDA violated Plaintiff's rights in this regard by failing to comply with FOIA's decision deadlines and thus constructively withholding information responsive to Plaintiff's FOIA requests.

136. Based on the nature of Plaintiff's professional activities, he will undoubtedly continue to employ FOIA's provisions in information requests to Defendant FDA in the foreseeable future.

137. Plaintiff's professional activities will be adversely affected if Defendant FDA is allowed to continue violating FOIA's disclosure provisions as it has in this case.

138. Unless enjoined and made subject to a declaration of Plaintiff's legal rights by this Court, Defendant FDA will continue to violate the rights of Plaintiff to receive public records under the FOIA.

139. Plaintiff is entitled to reasonable costs of litigation, including attorneys' fees and costs pursuant to FOIA. 5 U.S.C. § 552(a)(4)(E).

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COUNT II
VIOLATION OF THE FREEDOM OF INFORMATION ACT:
UNLAWFUL APPLICATION OF DISCLOSURE EXEMPTIONS

140. The allegations made in all preceding paragraphs are realleged and incorporated by reference herein.

141. Plaintiff has a statutory right to the records he seeks, and there is no legal basis for Defendant FDA to assert that any of FOIA's nine disclosure exemptions apply. *See* 5 U.S.C. § 552(b)(l)-(9).

142. Defendant FDA violated Plaintiff's rights in this regard by unlawfully withholding information responsive to Plaintiff's FOIA requests numbered 2014-3702, 2015-1143 and 2015-1144, based on the improper and overly broad application of FOIA's exemptions to mandatory information disclosure.

143. Based on the nature of Plaintiff's professional activities, he will undoubtedly continue to employ FOIA's provisions in information requests to Defendant FDA in the foreseeable future.

144. Plaintiff's professional activities will be adversely affected if Defendant FDA is allowed to continue violating FOIA's disclosure provisions as it has in this case.

145. Unless enjoined and made subject to a declaration of Plaintiff's legal rights by this Court, Defendant FDA will continue to violate the rights of Plaintiff to receive public records under the FOIA.

146. Plaintiff is entitled to reasonable costs of litigation, including attorneys' fees and costs pursuant to FOIA. 5 U.S.C. § 552(a)(4)(E).

COUNT III
VIOLATION OF THE FREEDOM OF INFORMATION ACT:
DECISION DEADLINE VIOLATION

147. The allegations made in all preceding paragraphs are realleged and incorporated by reference herein.

148. Plaintiff has a statutory right to have Defendant FDA process his FOIA requests in a

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manner which complies with FOIA. Plaintiff's rights in this regard were violated when the Defendant FDA unlawfully delayed its response to his information requests and appeals beyond the determination deadlines imposed by the FOIA. 5 U.S.C. §§ 552(a)(6)(A)(i), (ii).

149. Defendant FDA is unlawfully withholding public disclosure of information sought by Plaintiff, information to which he is entitled and for which no valid disclosure exemption applies.

150. Based on the nature of Plaintiff's professional activities, he will undoubtedly continue to employ FOIA's provisions in information requests to Defendant FDA in the foreseeable future.

151. Plaintiff's professional activities will be adversely affected if Defendant FDA is allowed to continue violating FOIA's decision deadlines as it has in this case.

152. Unless enjoined and made subject to a declaration of Plaintiff's legal rights by this Court, Defendant FDA will continue to violate the rights of Plaintiff to receive public records under the FOIA.

153. Plaintiff is entitled to reasonable costs of litigation, including attorney fees pursuant to FOIA. 5 U.S.C. § 552(a)(4)(E).

COUNT IV
VIOLATION OF THE FREEDOM OF INFORMATION ACT:
INADEQUATE SEARCH

154. The allegations made in all preceding paragraphs are realleged and incorporated by reference herein.

155. Plaintiff has a statutory right to have Defendant FDA process his FOIA requests in a manner which complies with FOIA. Plaintiff's rights in this regard were violated when the Defendant FDA unlawfully failed to undertake a search reasonably calculated to locate records responsive to Plaintiff's FOIA request numbered 2014-3702.

156. Defendant FDA is unlawfully withholding public disclosure of information sought by Plaintiff, information to which he is entitled and for which no valid disclosure exemption applies.

157. Based on the nature of Plaintiff's professional activities, he will undoubtedly continue to

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employ FOIA's provisions in information requests to Defendant FDA in the foreseeable future.

158. Plaintiff's professional activities will be adversely affected if Defendant FDA is allowed to continue violating FOIA by performing inadequate information searches as it has in this case.

159. Unless enjoined and made subject to a declaration of Plaintiff's legal rights by this Court, Defendant FDA will continue to violate the rights of Plaintiff to receive public records under the FOIA.

160. Plaintiff is entitled to reasonable costs of litigation, including attorney fees pursuant to FOIA. 5 U.S.C. § 552(a)(4)(E).

COUNT V
VIOLATION OF THE FREEDOM OF INFORMATION ACT:
FAILURE TO COMPLY WITH 5 U.S.C. § 552(a)(7)(B)(ii)

161. The allegations made in all preceding paragraphs are realleged and incorporated by reference herein.

162. Pursuant to 5 U.S.C. § 552(a)(7)(B)(ii), "Each agency shall . . . establish a phone line or Internet service that provides information about the status of a request to the person making the request . . . including . . . an estimated date on which the agency will complete action on the request."

163. Plaintiff asked FDA numerous times for estimated dates of completion for his pending FOIA requests and appeals. In so doing, Plaintiff invoked 5 U.S.C. § 552(a)(7)(B)(ii).

164. Defendant FDA has repeatedly failed to provide estimated dates of completion for Plaintiff's FOIA requests and appeals at issue in this case.

165. Upon information and belief, FDA's failure to provide specific estimated dates of completion for Plaintiff's FOIA requests and appeals represents an ongoing policy, practice, or standard operating procedure ("SOP").

166. A policy, practice, or SOP of refusing to provide estimated dates of completion to requesters is in violation of FOIA. Such a practice constitutes outrageous conduct for purposes of

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the broad equitable powers provided by FOIA to the Court. Such a policy is arbitrary, capricious, an abuse of discretion, or otherwise contrary to law.

167. Based on the nature of Plaintiff's professional activities, he will undoubtedly continue to employ FOIA's provisions in information requests to Defendant FDA in the foreseeable future.

168. Plaintiff's professional activities will be adversely affected if Defendant FDA is allowed to continue violating FOIA's requirement to provide estimated completion dates as it has in this case.

169. Unless enjoined and made subject to a declaration of Plaintiff's legal rights by this Court, Defendant FDA will continue to violate the rights of Plaintiff to receive public records under the FOIA.

170. Plaintiff is entitled to reasonable costs of litigation, including attorney fees pursuant to FOIA. 5 U.S.C. § 552(a)(4)(E).

COUNT VI
VIOLATION OF THE ADMINISTRATIVE PROCEDURES ACT

171. The allegations made in all preceding paragraphs are realleged and incorporated by reference herein.

172. Defendant FDA has failed to act in an official capacity under color of legal authority by failing to comply with the mandates of FOIA consequent to its failure and refusal to issue a timely final determination on Plaintiff's administrative requests and appeals, to a search reasonably calculated to locate records responsive to Plaintiff's FOIA request numbered 2014-3702, and to provide Plaintiff with a specific estimated completion date of his FOIA requests and appeals.

173. Defendant FDA has unlawfully withheld agency action by failing to comply with the mandates of FOIA consequent to its failure and refusal to: (1) provide to Plaintiff documents responsive to his information requests and appeals that are not within the scope of any of FOIA's disclosure exemptions; (2) issue a timely final determination of Plaintiff's administrative re-

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quests and appeals; (3) undertake a search reasonably calculated to locate records responsive to Plaintiff's FOIA request numbered 2014-3702, and; (4) provide Plaintiff with the estimated completion dates of those requests and appeals.

174. Plaintiff has been adversely affected and aggrieved by the Defendant FDA's failure to comply with the mandates of FOIA. Defendant's failure and refusal to: (1) provide to Plaintiff documents responsive to his information requests and appeals that are not within the scope of any of FOIA's disclosure exemptions; (2) issue a timely final determination of Plaintiff's administrative requests and appeals; (3) undertake a search reasonably calculated to locate records responsive to Plaintiff's FOIA request numbered 2014-3702, and; (4) provide Plaintiff with the estimated completion dates of those requests and appeals, has injured Plaintiff's interests in public oversight of governmental operations and constitute a violation of Defendant FDA's statutory duties under the APA.

175. Plaintiff has suffered a legal wrong as a result of the Defendant FDA' failure to comply with the mandates of FOIA. Defendant FDA's failure and refusal to: (1) provide to Plaintiff documents responsive to his information requests and appeals that are not within the scope of any of FOIA's disclosure exemption; (2) issue a timely final determination on Plaintiff's administrative requests and appeals; (3) undertake a search reasonably calculated to locate records responsive to Plaintiff's FOIA request numbered 2014-3702, and; (4) provide Plaintiff with the estimated completion dates of those requests and appeals, has injured Plaintiff's interests in public oversight of governmental operations and constitute a violation of Defendant FDA's statutory duties under the APA.

176. Defendant FDA's failure and refusal to: provide to Plaintiff documents responsive to his information requests and appeals that are not within the scope of any of FOIA's disclosure exemptions, and; (2) issue a timely final determination on Plaintiff's administrative requests and

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Eugene, OR 97402
(541) 556-6439

appeals; (3) undertake a search reasonably calculated to locate records responsive to Plaintiff's FOIA request numbered 2014-3702, and; (4) provide Plaintiff with the estimated completion dates of those requests and appeals, constitutes agency action unlawfully withheld and unreasonably delayed and is therefore actionable pursuant to the APA, 5 U.S.C. § 706(1).

177. Alternatively, Defendant FDA's failure and refusal to: (1) provide to Plaintiff documents responsive to its information requests and appeals that are not within the scope of any of FOIA's disclosure exemptions, and; (2) issue a timely final determination on Plaintiff's administrative requests and appeals; (3) undertake a search reasonably calculated to locate records responsive to Plaintiff's FOIA request numbered 2014-3702, and; (4) provide Plaintiff with the estimated completion dates of those requests and appeals, is in violation of FOIA's statutory mandates and is therefore arbitrary, capricious, or an abuse of discretion and not in accordance with law and is therefore actionable pursuant to the APA, 5 U.S.C. § 706(2).

178. Plaintiff is entitled to judicial review under the Administrative Procedure Act 5 U.S.C. §§ 702, 706.

179. Plaintiff is entitled to costs of disbursements and costs of litigation, including reasonable attorney and expert witness fees, under the Equal Access to Justice Act, 28 U.S.C.S. § 2412.

REQUESTS FOR RELIEF

WHEREFORE, Plaintiff prays that this Court:

1. Order Defendant in the form of injunctive relief to promptly provide Plaintiff all of the information sought in this action;

2. Declare Defendant's failure to disclose the information requested by Plaintiff to be unlawful under the FOIA, 5 U.S.C. § 552(a)(3), as well as agency action unlawfully withheld and unreasonably delayed, 5 U.S.C. § 706(1), and/or arbitrary, capricious, an abuse of discretion,

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and not in accordance with law, 5 U.S.C. § 706(2);

3. Declare Defendant's failure to make a timely determination on Plaintiff's administrative requests and appeals to be unlawful under the FOIA, 5 U.S.C. § 552(a)(6)(A)(i), as well as agency action unlawfully withheld and unreasonably delayed, 5 U.S.C. § 706(1), and/or arbitrary, capricious, an abuse of discretion, and not in accordance with law, 5 U.S.C. § 706(2);

4. Declare Defendant's failure to undertake a search reasonably calculated to locate records responsive to Plaintiff's FOIA request numbered 2014-3702 to be unlawful under the FOIA, 5 U.S.C. § 552(a)(6)(A)(i), as well as agency action unlawfully withheld and unreasonably delayed, 5 U.S.C. § 706(1), and/or arbitrary, capricious, an abuse of discretion, and not in accordance with law, 5 U.S.C. § 706(2);

5. Declare Defendant's failure to provide Plaintiff with the estimated completion dates of his requests and appeals, to be unlawful under the FOIA, 5 U.S.C. § 552(a)(7)(B)(i), as well as agency action unlawfully withheld and unreasonably delayed, 5 U.S.C. § 706(1), and/or arbitrary, capricious, an abuse of discretion, and not in accordance with law, 5 U.S.C. § 706(2);

6. Award Plaintiff its costs and reasonable attorney fees pursuant to 5 U.S.C. § 552(a)(4)(E) and 28 U.S.C. § 2412, or any other applicable law;

7. Expedite this action in every way pursuant to 28 U.S.C. § 1657(a); and

8. Grant such other and further relief as the Court may deem just and proper.

Respectfully submitted for the Court's consideration, this 14th day of July, 2015.

s/ David Bahr
David Bahr (Oregon Bar No. 901990)
(*pro hac vice* pending)
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