Scharf-Norton Center for Constitutional Litigation at the GOLDWATER INSTITUTE
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Attorneys for Plaintiff

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

GOLDWATER INSTITUTE, Plaintiff, vs. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendant.	No. **COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF**

1. This is an action under the Freedom of Information Act, 5 U.S.C. § 552, ("FOIA") for injunctive and other appropriate relief and seeking the disclosure of agency records improperly withheld from Plaintiff Goldwater Institute ("Goldwater Institute") by Defendant United States Health and Human Services ("HHS") and its component United States Food and Drug Administration ("FDA") (collectively, "Defendant").

Jurisdiction and Venue

2. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331.

3. Venue lies in this district under 5 U.S.C. § 552(a)(4)(B).

Parties

4. Plaintiff Goldwater Institute is a public interest non-profit research and policy organization with its principal place of business located in Phoenix, Arizona. It was established in 1988 to focus public attention on matters of public policy and constitutional governance. Among other issues, the Goldwater Institute has advocated for open and transparent government, and has provided extensive research and analysis on the drug approval process in the United States.

5. Defendant HHS is an agency of the Executive Branch of the United States Government within the meaning of 5 U.S.C. § 552(f)(1), and includes component entity FDA.

6. Defendant has possession and control over the records Plaintiff seeks under the FOIA.

Defendant's Denial of Plaintiff's Request

7. The FDA has broad regulatory authority to approve the manufacturing, shipment in interstate commerce, and marketing of all new drugs in the United States.

8. Under federal law, manufacturers of new drugs must receive FDA approval prior to the lawful shipment of investigational new drugs across state lines.

9. Under federal law, the FDA must approve investigational new drugs for human use.

10. In order to ship investigational new drugs across state lines, drug manufacturers or other drug sponsors must file and the FDA must approve an Investigational New Drug ("IND") application.

11. In order to administer investigational new drugs to humans, the investigational drug must be the subject of an approved IND application.

12. On August 5, 2014, CNN reported that two American doctors, Kent Brantly and Nancy Writebol, were successfully treated with an experimental drug, ZMapp. Sanjay Gupta and Danielle Dellorto, *Experimental Drug Likely Saved Ebola*

Patients, CNN, August 5, 2014 *available at* http://www.cnn.com/2014/08/04/health/experimental-ebola-serum.

13. ZMapp is an investigational drug that has not been approved by the FDA for marketing in the United States.

14. On information and belief, on or about August 7, 2014, ZMapp was not the subject of an approved IND application.

15. On information and belief, on or about August 7, 2014, ZMapp had not been tested on humans in clinical trials.

16. On information and belief, the FDA must approve ZMapp for human use prior to the drug's administration to humans.

17. On information and belief, the FDA must approve the shipment of ZMapp across state lines.

18. By letter dated August 7, 2014, the Goldwater Institute requested "Any and all records that indicate the approval process, deliberations made during that process, and final approval records regarding provision or approval of the drug and serum 'ZMapp' to be administered to Dr. Kent Brantly and Ms. Nancy Writebol, or any other individuals suspected to be infected with the Ebola virus, under the 'compassionate use' process or any other approval process at the FDA." A copy of this letter is attached as **Exhibit 1**.

19. The Goldwater Institute expressly requested records about the FDA's own internal drug approval process, not commercial information.

20. In its FOIA request of August 7, 2014, the Goldwater Institute requested a waiver of fees pursuant to 5 U.S.C. § 552(a)(4)(A)(iii).

21. By letter dated August 18, 2014, the FDA approved the Goldwater Institute's request for a waiver of fees. **Exhibit 2.**

22. By letter dated September 29, 2014, the Goldwater Institute was denied access to the requested information in its entirety on the grounds that it was exempt from disclosure under Exemption 4, 5 U.S.C. § 552(b)(4), an exemption intended to protect

trade secrets and other confidential commercial information. A copy of this letter is attached as **Exhibit 3**.

23. In its denial letter of September 29, 2014, the FDA identified nine volumes of responsive records that the FDA claimed were exempt from disclosure in their entirety.

24. By letter dated October 23, 2014, the Goldwater Institute appealed the denial of its FOIA request. A copy of this letter is attached as **Exhibit 4**.

25. By letter dated February 19, 2015, HHS denied the Goldwater Institute's administrative appeal. A copy of this letter is attached as **Exhibit 5**.

26. In its letter of February 19, 2015, in addition to exemption (b)(4), HHS claimed that the requested records were exempt from disclosure under Exemptions 3, 5, and 6, 5 U.S.C. §§ 552(b)(3), (b)(5), (b)(6).

27. Plaintiff has exhausted the applicable administrative remedies with respect to its FOIA request to Defendant.

Cause of Action

(Production Under the FOIA)

28. Plaintiff asserts and incorporates by reference paragraphs 1-27.

29. Plaintiff properly requested records within Defendant's control and possession in accordance with the FOIA.

30. Plaintiff has a right of access to the requested information under the FOIA, and there is no legal basis for Defendant's denial of such access.

31. Defendant has wrongfully withheld the requested records from Plaintiff.

32. Plaintiff exhausted its administrative remedies with regard to the wrongfully withheld records.

Requested Relief

WHEREFORE, Plaintiff requests this Court:

a. enjoin Defendant from withholding and order Defendant to disclose the requested records in their entireties and make copies available to Plaintiff;

b. declare that Defendant's failure to disclose the records requested by Plaintiff violates the FOIA;

c. enter a finding that personnel employed by Defendant acted arbitrarily and capriciously in withholding public records from Plaintiff as provided in 5 U.S.C. § 552(a)(4)(F);

d. award Plaintiff costs and reasonable attorneys' fees in this action, as provided in 5 U.S.C. § 552(a)(4)(E); and

e. grant such other and further relief as may deem just and proper.

RESPECTFULLY SUBMITTED this 9th day of June, 2015 by:

/s/ Jonathan Riches
Clint Bolick (021684)
Jonathan Riches (025712)
Courtney Van Cott (031507)
Scharf-Norton Center for Constitutional Litigation at the GOLDWATER INSTITUTE
Attorneys for Plaintiff

CERTIFICATE OF SERVICE

Document Electronically Filed by ECF this 9th day of June, 2015 to:

/s/ Kris Schlott
Kris Schlott

Exhibit 1

GOLDWATER
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August 7, 2014

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
12420 Parklawn Drive
ELEM-1029
Rockville, MD 20857

Re: Freedom of Information Act Request Regarding ZMapp Drug Approval

On behalf of the Scharf-Norton Center for Constitutional Litigation at the Goldwater Institute (the "**Goldwater Institute**") and pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, this correspondence is a request for records, regardless of format, medium or physical characteristics.

Specifically, we seek the following documents and records:

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

Electronic production of records and information is acceptable. If the records are produced electronically, please include all associated metadata. If you refer me to a website containing responsive records, please specify the precise web address where they may be found.

Please note that the Goldwater Institute is a not-for-profit 501(c)(3) organization. As such, no responsive records will be used for a commercial purpose. Therefore, we respectfully request a waiver of all fees associated with the production of responsive records pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) which reads as follows:

> *"Documents shall be furnished without any charge or at a charge reduced below the fees established under clause (ii) if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester."*

The Goldwater Institute conducts research and analysis on issues pertaining to government transparency and health care, among others. The Goldwater Institute is currently

Goldwater Institute | 500 East Coronado Rd., Phoenix, AZ 85004 | *Phone* (602) 462-5000 | *Fax* (602) 256-7045 | *email* info@goldwaterinstitute.org

engaged in research and analysis pertaining to the FDA drug approval process. This information will be used to aid in that research and analysis and is expected to contribute to the public's understanding of the drug approval process in the United States.

Should our request for a waiver be denied, we are willing to pay fees for this request up to two hundred dollars ($200.00). If you estimate that fees will exceed this amount, please inform me first.

I request your response within the statutory timeframe of twenty (20) business days. If you are unable to complete the request within that time, please contact me with your progress and expected completion date.

Please mail responsive records to the mailed address above or e-mail address below.

If you deny access to any of the above public records, please provide forthwith a written statement of the express grounds for the denial, citing the law or regulation under which access is denied.

If you have any questions about this request or foresee any problems in fully releasing the requested records please contact me as soon as possible. I can be reached at 602-462-5000 or jriches@goldwaterinstitute.org.

Thank you for your prompt attention to this request.

Sincerely,

Jon Riches
Attorney

Exhibit 2

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration AUG 18 2014 Rockville, MD 20857

Jonathan Riches
Goldwater Institute
500 E. Coronado Rd.
Phoenix, AZ 85004

In reply refer to: 2014-6596

Dear Requester:

This is in response to your Freedom of Information request (copy enclosed) for waiver of fees for documents requested under the Freedom of Information Act.

As provided by Food and Drug Administration regulations at 21 CFR 20.46, Department of Health and Human Services' regulations at 45 CFR 5.34, and based on your justification, a waiver of fees has been granted.

Sincerely Yours,

Frederick J. Sadler
Director
Division of Freedom of Information

Enclosures

Exhibit 3

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

Date: SEP 29 2014

Request Number: 2014-6596

Jonathan Riches
Goldwater Institute
500 E. Coronado Rd.
Phoenix, AZ 85004

Subject of Request: ZMapp

Dear Sir/Madam:

The Food and Drug Administration (FDA) has completed processing your request for records under the Freedom of Information Act (FOIA). I apologize for any delay in responding to you. The paragraphs checked below apply to your request:

[ ] We have already released certain materials to you and are denying the remainder of your request.

[X] We are denying your entire request.

[X] The following exemption(s) of FOIA, 5 U.S.C. 552, indicated by an "X" is/are the authority for denying you access to the non-disclosable material. We have enclosed copies of FOIA and regulations for your information.

- [ ] (b)(1) National security information concerning the national defense or foreign policy
- [ ] (b)(2) Internal rules and practices
- [ ] (b)(3) Prohibited from disclosure by other laws
- [X] (b)(4) Trade secret and confidential commercial information
- [ ] (b)(5) Certain interagency and intra-agency communications
- [ ] (b)(6) Information about individuals in personnel, medical and similar files when disclosure would constitute a clearly unwarranted invasion of privacy
- [ ] (b)(7) Records or information compiled for law enforcement purposes when disclosure
  - [ ] (A) could reasonably be expected to interfere with enforcement proceedings
  - [ ] (B) would deprive a person of a right to a fair trial or an impartial adjudication
  - [ ] (C) could reasonably be expected to constitute an unwarranted invasion of personal privacy

[ ] (D) could reasonably be expected to disclose the identity of a confidential source
[ ] (E) would disclose techniques, procedures or guidelines for law enforcement investigations or prosecutions, if such disclosure could reasonably be expected to risk circumvention of the law
[ ] (F) could reasonably be expected to endanger the life or physical safety of an individual

[**X**] The following section(s) of the implementing regulations of the Department of Health and Human Services (DHHS) applicable to this denial is/are indicated by an "X". The regulations are contained in the Code of Federal Regulations (CFR), Title 45.

[ ] 5.63
[ ] 5.64
[**X**] 5.65(c)
[ ] 5.66
[ ] 5.67
[ ] 5.68(a)
[ ] 5.68(b)
[ ] 5.68(c)
[ ] 5.68(d)
[ ] 5.68(e)
[ ] 5.68(f)
[ ] Other:

[**X**] The following section(s) of the implementing regulations of FDA and reason(s) applicable to this denial is/are indicated by an "X". The regulations are contained in the Code of Federal Regulations (CFR), Title 21.

[**X**] 20.61(b)(c), 312.130(b) and 314.430(d)(1) Trade Secret and confidential commercial information.

[**X**] FDA's Regulations at CFR Part 20 are available at:
http:www.access.gpo.gov/nara/cfr/waisidx_04/21cfr20_04.html

[**X**] Other laws, in addition to FOIA, may prohibit disclosure of the information you requested. The following law(s) applicable to this denial is/are indicated by an "X".

[**X**] 18 U.S.C. 1905 [Federal Trade Secrets Act]
[ ] 21 U.S.C. 301(j) [Federal Food, Drug, and Cosmetic Act].
[ ] 21 U.S.C. 360j(c) [Federal Food, Drug, and Cosmetic Act]
[ ] 5 U.S.C. 107(a)(2) Appendix 4 [Ethics in Government Act]

[**X**] The estimated volume of the records we are denying is: Nine volumes.

The Department of Health and Human Services' implementing regulations, 45 CFR 5.34, set forth the procedures for you to follow if you decide to appeal this decision not to provide you with the information you requested. Your appeal should be sent within 30 days from the date you receive this letter to the Deputy Agency Chief FOI Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Parklawn Building, Room 19-01, 5600 Fishers Lane, Rockville, MD 20857.

Sincerely yours,

Frederick J. Sadler
Director
Division of Freedom of Information

Exhibit 4

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October 23, 2014

Sent via Certified Mail Return Receipt Requested

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Attn. Deputy Agency Chief FOI Officer
Parklawn Building, Room 19-01
5600 Fishers Lane
Rockville, MD 20857

Re: Appeal of FOIA Denial ICO 2014-6596

On behalf of the Scharf-Norton Center for Constitutional Litigation at the Goldwater Institute (the "**Goldwater Institute**") and pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552 and 45 C.F.R. § 5.34, we hereby appeal the Food and Drug Administration's (the "**FDA**") complete denial of the Goldwater Institute's request for public records.

The FDA claims the Goldwater Institute's request for records is exempt from disclosure under 5 U.S.C. § 522(b)(4). The (b)(4) exemption protects trade secrets and confidential commercial information. That exemption is inapplicable to the Goldwater Institute's request for records pertaining to the FDA's *internal administrative review and approval process* pertaining to the apparent dispensation of an experimental drug, "ZMapp."

On August 7, 2014, the Goldwater Institute submitted a FOIA request (enclosure 1), including a request for the waiver of all fees pursuant to 5 U.S.C. § 522(a)(4)(A)(iii), to the FDA for:

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

On August 18, 2014, the FDA approved the waiver of fees request (enclosure 2).

By letter dated September 29, 2014, the Department of Health and Human Services ("DHHS") acknowledged having approximately nine (9) volumes of responsive records, but denied the Goldwater Institute's FOIA request in its entirety under exemption b(4) and other regulatory provisions. The denial was received by the Goldwater Institute on October 3, 2014.

As you are well aware, the FOIA and applicable regulatory guidance require open and transparent government. To that end, federal law favors the disclosure of records made and kept by federal agencies. *Bristol-Myers Co. v. FTC*, 424 F.2d 935, 938 (D.C. Cir. 1970) ("[T]he primary purpose of the Freedom of Information Act [is] to *increase* the citizen's access to government records") (emphasis added); s*ee also* Presidential Memorandum, 74 F.R. 4683 (Jan. 21, 2009). ("A democracy requires accountability, and accountability requires transparency. . . . The Freedom of Information Act should be administered with a clear presumption: In the face of doubt, openness prevails").

The FOIA specifically compels disclosure under certain circumstances. "Each agency *shall make available* to the public information as follows: . . . statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal and informal procedures available[.]" 5 U.S.C. § 552(a)(1)(B) (emphasis added). In this case, the Goldwater Institute is seeking records expressly pertaining to "the general course and method by which [the FDA's] functions are channeled and determined," including the formal and informal *internal* approval procedures by which the drug ZMapp was administered to two American patients. In other words, the Goldwater Institute seeks records pertaining to the government's own administrative processes as they were applied in particular instances. Pursuant to 5 U.S.C. § 552(a)(1)(B), among other provisions, the FOIA requires disclosure of these records.

Moreover, although the reason for the request need not be stated (*see* 45 C.F.R. § 5.34(b)), as indicated in the Goldwater Institute's initial FOIA request: "The Goldwater Institute conducts research and analysis on issues pertaining to government transparency and health care, among others. The Goldwater Institute is currently engaged in research and analysis pertaining to the FDA drug approval process. This information will be used to aid in that research and analysis and is expected to contribute to the public's understanding of the drug approval process in the United States." Opening administrative processes, such as the drug approval process in the United States, to the scrutiny of the general public for study and examination is one of the principal purposes of the FOIA. *See Renegotiation Bd. v. Bannercraft Clothing Co.*, 415 U.S. 1, 9, 94 S. Ct. 1028, 1033 (1974) (Purpose of the FOIA was primarily to open administrative processes to the scrutiny of the press and general public); *Pub. Citizen Health Research Grp. v. Food & Drug Admin.*, 185 F.3d 898, 904 (D.C. Cir. 1999) ("[The requester's] main reason for seeking this information is to 'review whether the FDA is adequately safeguarding the health of people who participate in drug trials'; the information sought, in other words, would reveal 'what the[ ]government is up to']) (internal citations omitted).

The 5 U.S.C. § 522(b)(4) exemption on which the FDA relies to deny these public records in their entirety is inapposite. As a general matter, exceptions to disclosure of records under 5 U.S.C. § 522(b) are to be narrowly construed. *Milner v. Dep't of Navy*, 131 S. Ct. 1259, 1262, 179 L. Ed. 2d 268 (2011) ("FOIA [ ] mandates that an agency disclose records on request, unless they fall within one of nine exemptions. These exemptions are 'explicitly made exclusive', and must be 'narrowly construed'") (internal citations omitted). The (b)(4) exemption, in particular, should be read narrowly to exempt only records that would undermine its specific and limited purpose. *Soucie v. David*, 448 F.2d 1067, 1078 (D.C. Cir. 1971) ("[The (b)(4) exemption] is intended to encourage individuals to provide certain kinds of confidential information to the Government, and it must be read narrowly in accordance with that purpose"). Additionally, the burden is on the government to prove that the records requested are exempt from disclosure under b(4). *See Gov't Accountability Project v. U.S. Dep't of Health & Human Servs.*, 691 F. Supp. 2d 170, 180 (D.D.Cir. 2010).

It appears the FDA is relying on a FOIA exemption, and implementing regulations,[1] that simply do not apply to the Goldwater Institute's request. Exemption b(4) permits an agency to withhold only two limited categories of records: trade secrets, and information that is "commercial or financial" that has been "obtained from a person" and that is "confidential" in nature. *See* 5 U.S.C. § 552(b)(4); *Pub. Citizen Health.*, 704 F.2d at 1288; *Gov't Accountability Project v. U.S. Dep't of Health & Human Servs.*, 691 F. Supp. 2d 170, 174-75 (D.D.C. 2010). The Goldwater Institute seeks neither trade secrets, nor confidential commercial information. As indicated, *supra*, the Goldwater Institute seeks only records pertaining to the FDA's own internal approval processes and procedures regarding dispensation of an experimental drug over which the FDA has apparent authority. This request simply does not fall within the definition of a "trade secret" as the Goldwater Institute is seeking no "plan, formula, process, or device" that is, *inter alia*, secret and "commercially valuable." *Pub. Citizen Health Research Grp. V. Food & Drug Admin.*, 704 F.2d 1280, 1288 (D.C. Cir. 1983). Additionally, the Goldwater Institute seeks records pertaining the government's own internal operations, the majority of which are presumably prepared by the government; records that by their very nature cannot be commercial, as the government ostensibly has no proprietary interest in its own internal review and approval processes. *Gov't Accountability Project*, 691 F. Supp. 2d at 174-75.

Finally, to the extent any records contain information to which the b(4) exemption is actually applicable, the FDA was and is required to evaluate alternatives to full disclosure. *See Grumman Aircraft Eng'g Corp. v. Renegotiation Bd.*, 425 F.2d 578, 580-81 (D.C. Cir. 1970); *see also Gov't Accountability Project*, 691 F. Supp. 2d at 181 ("[T]he Court must ensure that the government has disclosed all reasonably segregable information"). In this case, the FDA has withheld documents contained in *nine volumes* in their entirety. Based on the size of the responsive records alone, it does not appear as though the FDA has evaluated alternatives to full disclosure such as partial disclosure or selective redaction.

Based on the foregoing, the Goldwater Institute requests that this appeal be granted and that all responsive records pertaining to the Institute's FOIA request dated August 7, 2014 be released without delay.

Should you have any questions regarding this appeal, please do not hesitate to contact me at 602-462-5000 or jriches@goldwaterinstitute.org.

Thank you for your prompt attention to this matter.

Sincerely,

Jon Riches
Attorney

[1] The FDA also cites several implementing regulations in its denial letter to the Goldwater Institute's request for public records; viz., 21 C.F.R. §§ 20.61(b)-(c), 312.130(b), 314.430(d)(1) and 21 C.F.R. Part 20. The regulatory provisions cited by the FDA either track the statutory language of 5 U.S.C. § 552(b)(4) and relevant case law, and thus fall under the analysis set out in this appeal, or are too vague and ambiguous in terms of their application to the records request for the Goldwater Institute to meaningfully respond to the basis for denial. To the extent denial was based on foregoing implementing regulations, rather than the b(4) exemption cited, the Goldwater Institute requests a sufficiently clear statement of denial and the reasons therefor, or other appropriate explanation, so as to permit any necessary response.

Exhibit 5

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Public Affairs
Washington, D.C. 20201

February 19, 2015

Appeal No.: 15-0043
FDA File No.: 2014-6596

Mr. Jon Riches
The Goldwater Institute
500 East Coronado Road
Phoenix, AZ 85004

Dear Mr. Riches:

I am responding to your letter, dated October 23, 2014, in which you appealed the response you received from the Food and Drug Administration (FDA) regarding your Freedom of Information Act (FOIA) request. Your request sought records that "indicate the approval process, deliberations made during that process, and final approval records regarding provisions or approval of the drug and serum "ZMapp" to be administered to Dr. Kent Brantly and Ms. Nancy Writebol, or any other individuals suspected to be infected with the Ebola virus, under the "compassionate use"[1] process or any other approval process at the FDA."

By letter dated September 29, 2014, FDA responded to your request, denying it in its entirety pursuant to Exemption 4 of the FOIA, 18 U.S.C. § 1905 (Federal Trade Secrets Act), Department of Health and Human Service (HHS) regulation 45 CFR 5.65(c), and FDA regulations at 21 C.F.R. parts 20.61(b)(c), 312.130(b), and 314.430(d)(1).

You appealed FDA's full denial stating that Exemption 4 does not apply to your request because your request does not fall within the definition of a trade secret or confidential commercial information. You stated that your request sought records pertaining to the government's own internal operations, and those records by their very nature cannot be commercial. Finally, you stated that if Exemption 4 is applicable to certain information within the records, FDA is required to segregate the information.

Information you requested is contained in an unapproved Investigational New Drug (IND) application. FDA denied your request because ZMapp is still in the IND phase and has not been approved for marketing. Specifically, FDA's regulations at 21 C.F.R. 312.130 and 314.430 set forth what information in INDs can be disclosed to the public. These regulations generally prohibit the release of any data or information in an unapproved application, even if the existence of the application has been publicly disclosed by the sponsor. Pursuant to 21 C.F.R. 312.130(b), the public disclosure of data and information in INDs is governed by 21 C.F.R. 314.430, which

[1] For information regarding investigational new drug applications, see http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm. FDA's webpage containing its Ebola response updates can be found at http://www.fda.gov/emergencypreparedness/counterterrorism/medicalcountermeasures/ucm410308.htm.

states that "[i]f the existence of an application... has been publicly disclosed or acknowledged before the agency sends an approval letter to the applicant, no data or information contained in the application... is available for public disclosure before the agency sends an approval letter..."[2] The product at issue here is not the subject of an approved New Drug Application (NDA), but rather the subject of an IND that is still undergoing review for approval. The language of the regulation expressly prohibits the release of any information in the application, preventing FDA from segregating the confidential commercial information from the non-confidential commercial information within the application.

As stated above, FDA withheld the information responsive to your request under Exemption 4; however, I find that the information also should have been withheld pursuant to Exemptions 3, 5, 6, and various HHS and FDA regulations, as discussed below.

Exemption 4 and the Trade Secrets Act

Exemption 4 of the FOIA[3] exempts from public disclosure trade secrets and commercial or financial information obtained from a person and that is privileged or confidential. The Trade Secrets Act, 18 U.S.C. §1905, prohibits the disclosure of both trade secret and confidential commercial information, unless such disclosure is authorized by law. The scope of information covered by the Trade Secrets Act is the same as that covered by Exemption 4 of the FOIA; the Trade Secrets Act and Exemption 4 are "coextensive."

The standard for whether "commercial or financial information" is considered to be "confidential" for purposes of Exemption 4 turns on whether it is a mandatory or a voluntary submission to the government. For mandatory submissions, commercial or financial information is "confidential" for purposes of Exemption 4 if disclosure of the information is likely either "to impair the Government's ability to obtain necessary information in the future; or to cause substantial harm to the competitive position of the person from whom the information was obtained."[4]

Given that sponsors must provide information in order to submit an IND,[5] disclosure is unlikely to discourage the flow of information to the agency. Therefore, the standard that applies to data and information in INDs is whether its disclosure is likely to cause substantial competitive harm to the submitter.

Courts have agreed with FDA that information in a pending product application is confidential commercial information under Exemption 4 and the Trade Secrets Act. As one court explained, "a drug manufacturer which has submitted [a new drug application, or] NDA has a competitive interest in seeing that the information contained in its NDA is not prematurely released to the public. If a manufacturer's competitor could obtain all the data in the manufacturer's NDA, it could utilize them in its own NDA without incurring the time, labor, risk, and expense involved in developing them independently."[6]

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[2] 21 C.F.R. 314.430(d)(1).
[3] 5 U.S.C. § 552(b)(4).
[4] National Parks & Conservation Ass'n v. Morton, 498 F.2d 765 (D.C. Cir. 1974).
[5] The requirements for submitting an IND are set forth in FDA's regulations at 21 C.F.R. parts 312.
[6] *Webb v. HHS*, 696 F.2d 101, 103 (D.C. Cir. 1982).

Additionally, HHS regulations at 45 C.F.R. Section 5.65 state that the Department will withhold trade secrets and commercial or financial information that is obtained from a person and is privileged or confidential. Likewise, FDA's own disclosure regulations at 21 C.F.R. 20.61 prohibit the disclosure of "[d]ata and information submitted or divulged to the [FDA] which fall within the definitions of a trade secret or confidential commercial or financial information [as defined in 21 C.F.R. §§20.61(a) and (b)]."

Exemption 3 and the Federal Food, Drug, and Cosmetic Act

Exemption 3 of the FOIA exempts from disclosure information prohibited from disclosure by another statute. Section 301(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)[7] has been recognized as an Exemption 3 statute. Section 301(j) prohibits revealing "any information" acquired under the authority of Section 505 of the FD&C Act "concerning any method or process which as a trade secret is entitled to protection." INDs are also required to contain – or incorporate by reference – chemistry, manufacturing, and controls (CMC) information, which includes trade secret information. Such CMC information is acquired under the authority of Section 505(i) of the FD&C Act. Therefore, FDA should have cited Exemption 3 in its September 29, 2014, letter to protect the CMC information incorporated into the INDs.

Exemption 5

Your request also sought records that indicate the approval process, deliberations made during that process, and final approval records regarding provision or approval of ZMapp. Exemption 5 of the FOIA protects "inter-agency or intra-agency memoranda or letters which would not be available by law to a party other than an agency in litigation with the agency;" this includes information subject to the deliberative process privilege, which permits the government to withhold documents that are both predecisional and deliberative.

Courts have established two requirements that must be met for the deliberative process privilege to be invoked on inter- or intra-agency communications. First, the communication must be pre-decisional, i.e., antecedent to the adoption of the agency's policy. Second, the communication must be deliberative, i.e., a direct part of the deliberative process in that it makes recommendations or expresses opinions on legal or policy matters.

The deliberative process privilege of Exemption 5 permits the government to withhold documents that reflect advisory opinions, recommendations, and deliberations comprising part of the process by which government decisions and policies are formulated. The purpose of FOIA Exemption 5 is to prevent injury to the quality of agency decisions by ensuring that agency staff can be free to express their honest opinions on policy matters. It is intended to promote frank and independent discussion among those responsible for making governmental decisions.

Documents exempt from disclosure under Exemption 5 are also exempt from disclosure under 21 CFR §20.62. Deliberative process information is similarly withheld under HHS regulations at 45 CFR §5.66.

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[7] 21 U.S.C. §331(j).

With regard to the documents responsive to your request, documents withheld pursuant to Exemption 5 include intra-agency communications that contain predecisional and deliberative information about agency determinations made in response to IND requests. Any such documents and information fall squarely within the deliberative process privilege and are exempt from disclosure under Exemption 5. Therefore, FDA should have cited Exemption 5 in its September 29, 2014, letter to protect the deliberative portions of the pending application.

Exemption 6

You also requested information regarding "provision or approval of the drug and serum 'ZMapp' to be administered to" specific individuals "suspected to be infected with the Ebola virus." Exemption 6 permits the withholding of information about individuals in "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy."[8] FDA's regulations at 21 CFR §20.63 and HHS regulations at 45 CFR §5.67 protect the same scope of information.

To warrant protection under Exemption 6, information and records must first meet a threshold requirement of "personnel and medical files and similar files." The term "similar files" is to be interpreted broadly. Courts have held that all information that applies to a particular individual meets this threshold requirement. In this case, that threshold has been met, as the information withheld under Exemption 6 pertains to particular persons (e.g., the names of individuals or other personally identifying information).

Whether release of information would constitute a clearly unwarranted invasion of personal privacy first requires analysis of whether public access to the information would violate a viable privacy interest of the individual. Individuals have a cognizable interest in their medical information and the requested information includes medical information pertaining to specific patients. Although in theory it may be possible to redact personally identifying information from medical information in such a manner as to protect an individual's privacy right, the information you have requested pertains to an investigational product being studied under a pending IND and, as discussed above, such information is exempt from disclosure under Exemption 4 and other applicable statutory and regulatory provisions.

Even if there is a cognizable privacy interest, the information may only be withheld if the individual privacy concerns outweigh the public interest in disclosure. In your request and appeal, you note that the requested information will be used to aid in "research and analysis pertaining to the FDA drug approval process" and "is expected to contribute to the public's understanding of the drug approval process in the United States." There is a public interest in information about FDA's implementation of its statutory and regulatory authorities with regard to the drug approval process. However, you have not provided any justification as to why that public interest would outweigh the privacy interests in this situation. Therefore, FDA should have cited Exemption 6 in its September 29, 2014, letter.

In conclusion, in light of the fact that the requested information is contained in pending INDs and pursuant to Exemptions 3, 4, 5, 6 of the FOIA, the Trade Secrets Act, and FDA's regulations

[8] 5 U.S.C. § 552(b)(6).

at 21 C.F.R. 20.61, 20.62, 20.63, 312.130(b), and 314.430, the requested information contained in the application is not available for public disclosure.

This letter constitutes the final decision of the Department in this matter. If you wish, you may seek judicial review in the district court of the United States in the district in which you reside or have your principal place of business, in which the agency records are located, or in the District of Columbia.

The 2007 FOIA amendments created the Office of Government Information Services (OGIS) to offer mediation services to resolve disputes between FOIA requesters and Federal agencies as a non-exclusive alternative to litigation. Using OGIS services does not affect your right to pursue litigation. You may contact OGIS in any of the following ways: Telephone: (202) 741-5770; Facsimile: (202) 741-5769; E-mail: ogis@nara.gov; or U.S. Mail at:

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Sincerely,

Catherine Teti

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