OFFICE of GOVERNMENT INFORMATION SERVICES

NATIONAL ARCHIVES and RECORDS ADMINISTRATION

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October 30, 2015—sent via email

[redacted]

Re: Case No.: 201500246
NG: KM

Dear [redacted]:

This responds to a request for assistance from the Office of Government Information Services (OGIS) submitted to us by your former colleague, Natalie M. Mackiel, on December 19, 2014. I apologize for the delay in formally responding to your request for assistance.

Congress created OGIS to complement existing Freedom of Information Act (FOIA) practice and procedure; we strive to work in conjunction with the existing request and appeal process. The goal is for OGIS to allow, whenever practical, the requester to exhaust his or her remedies within the agency, including the appeal process.

OGIS has no investigatory or enforcement power, nor can we compel an agency to release documents. OGIS serves as the Federal FOIA Ombudsman and our jurisdiction is limited to assisting with the FOIA process.

The Freedom of Information Act (FOIA) request for which [redacted] sought assistance was [redacted] to the Food and Drug Administration (FDA) seeking access to documents concerning communications between FDA [redacted]. about an application [redacted] I note that the Department of Health and Human Services (HHS), in response to [redacted], affirmed FDA's use of FOIA Exemption 4, 5 U.S.C. § 552(b)(4), to fully withhold five pages of records.

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As HHS informed you in its appeal response, the records you seek concern an application for expanded use of a drug, the expansion of which FDA has not approved. OGIS discussed this request with HHS and FDA, which re-reviewed its response to the request and appeal. The agency is firm in its position that the five pages [redacted] seeks contain trade secrets and confidential commercial information, the very information that Exemption 4 was designed to shield from disclosure.

Exemption 4 provides protection to submitters who furnish commercial or financial information to the government by insulating them from competitive disadvantages that may result from disclosure. To qualify for Exemption 4 protection, the information must be a trade secret or commercial or financial information, and it must

be obtained from a person (this includes corporations) and contain privileged or confidential information.

As HHS informed you, courts have long held that information in an unapproved drug application is exempt from disclosure under FOIA Exemption 4.

In [redacted] request for OGIS assistance, she noted that [redacted] and FDA have made significant public statements regarding the communications between the two parties. However, those public statements do not limit the agency's ability to withhold the documents under Exemption 4. Please know that the agency does not have discretion to release a record that falls under Exemption 4. The exemption does not include a public interest component, meaning that even if information might be of interest to the public, the agency must withhold any record or portion of a record covered by the exemption.

With regard to your request for access to information from the FDA as it relates to litigation, FOIA and the discovery process provide entirely different processes for obtaining information from the Federal Government. FOIA provides a general right of public access to records, while discovery offers a tool used during litigation to obtain information, usually from an opposing party. While FOIA may be used in conjunction with discovery, federal courts have "well established that a FOIA requester cannot rely upon his status as a private party litigant—in either civil or criminal litigation—to claim an entitlement to a greater FOIA access than would be available to the average requester." (Department of Justice FOIA Update, Vol. VI, No. 3, 1985, http://www.justice.gov/oip/foia_updates/Vol_VI_3/page5.htm)

I understand that you recently informed OGIS that the records you seek, filed under seal in U.S. District Court, were recently unsealed and that action should allow FDA to lift its use of Exemption 4. Once the FOIA administrative process ends, agencies generally do not re-process requests; this is particularly true at agencies processing many requests such as FDA, which processed 10,191 requests in the year ending September 30, 2014, the latest year for which data is available.

I hope this information is useful to you. In cases such as this where an agency is firm in its position, there is little for OGIS to do beyond providing more information about the agency's actions. At this time, there is no further assistance OGIS can offer. I again apologize for taking so long to respond. Thank you for bringing this matter to OGIS. We will close your case.

Sincerely,

/S/

JAMES V.M.L. HOLZER
Director

We appreciate your feedback. Please visit https://www.surveymonkey.com/s/OGIS to take a brief anonymous survey on the service you received from OGIS.