



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



FOIA Request 2023-0246

Freedom of Information Act Office
Cohen Bldg., Suite 5527
330 Independence Ave., SW
Washington DC 20201

January 18, 2023

By Email.

Taylor Stoneman
American Oversight
1030 15th Street NW, Ste B255
Washington, DC 20005
Email: foia@americanoversight.org

Dear Taylor Stoneman:

This is in response to the February 2, 2022, Freedom of Information Act (FOIA), request you originally submitted to the Department of Health and Human Services (HHS), and received in the Office of Inspector General (OIG), on January 4, 2023, seeking a copy of all final documents produced by the HHS OIG during its investigation into the FDA's approval of Aduhelm and the agency's interactions with Biogen staff in the months leading up to the drug's approval.

I can neither confirm nor deny the existence of records which would be responsive to your request. If they exist, records of this nature would be exempt from disclosure under FOIA Exemptions (b)(4), (b)(5), (b)(6), (b)(7)(A), (b)(7)(C) and/or (b)(7)(F). These exemptions, exempt from mandatory disclosure records compiled for law enforcement proceedings, if disclosure could reasonably be expected to interfere with enforcement proceedings; internal government records which are pre-decisional and contains staff advice, opinion and recommendations; as well as commercial or financial information that was obtained from a person or organization outside the government and that is privileged or confidential.

Exemption (b)(4) permits the withholding of commercial or financial information that was obtained from a person or organization outside the government and that is privileged or confidential.

Exemption (b)(5) permits the withholding of internal government records which are pre-decisional and contains staff advice, opinion and recommendations. This exemption is intended to preserve free and candid internal dialogue leading to decision making.

Exemption (b)(6) permits the withholding of information that if released, would constitute a clearly unwarranted invasion of personal privacy. Additionally, I have reviewed and weighed the public interest in disclosure of this information against the privacy interest in nondisclosure and found that the privacy interest outweighs the public's interest in disclosure.

Exemption (b)(7)(A) permits the withholding of investigatory records compiled for law enforcement purposes when disclosure could reasonably be expected to interfere with enforcement proceedings.

Exemption (b)(7)(C) permits the withholding of investigatory records compiled for law enforcement purposes when disclosure could reasonably be expected to constitute an unwarranted invasion of personal privacy.

Exemption (b)(7)(F) permits the withholding of law enforcement-related information necessary to protect the physical safety of a wide range of individuals. This exemption provides broad protection to "any individual" when disclosure of information about him "could reasonably be expected to endanger life or physical safety."

There is no charge for FOIA services in this instance because billable fees are under the Department's \$25.00 cost effective threshold.

If you have reason to believe that any denied portions should not be exempt from disclosure, you may appeal. Your appeal must be electronically transmitted within 90 days from the date of this letter using the HHS [Public Link](#) or email HHS_FOIA_Public_Liaison@hhs.gov with courtesy copy to [OIG FOIA Appeal](#). Clearly include in your subject line "Freedom of Information Act Appeal".

In addition, you may contact our FOIA Requester Service Center at 202.619.2541 or FOIA@oig.hhs.gov, for any further assistance or to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, Room 2510, 8601 Adelphi Road, College Park, Maryland 20740-6001, ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

For your information, Congress excluded three discrete categories of law enforcement and national security records from the requirements of the FOIA. See 5 U.S.C. § 552(c) (2006 & Supp. IV (2010)). This response is limited to those records that are subject to the requirements of the FOIA. This is a standard notification that is given to all our requesters and should not be taken as an indication that excluded records do, or do not, exist.

Sincerely,


Robin R. Brooks
Director
Freedom of Information