U.S. FOOD & DRUG ADMINISTRATION

May 15, 2024

Via Email: tina@cbsnews.com

Subject of Request: Freedom of Information Act (FOIA) Request 2024-4099

Dear Requester:

The Food and Drug Administration (FDA) has completed processing your May 6, 2024, request for records under the Freedom of Information Act (FOIA), in which you sought:

> *Records documenting the collection or testing of samples from suspected counterfeit Botox products referenced in this post: https://www.fda.gov/drugs/drug-safety-and-availability/counterfeit-version-botox-found-multiple-states.*

We are denying your entire request. Specifically, we are withholding records from an investigative case file in accordance with:

> 5 U.S.C. § 552 (b)(7)(A), which allows us to withhold records or information compiled for law enforcement purposes when disclosure could reasonably be expected to interfere with enforcement proceedings.

The following Department of Health and Human Services (HHS) and FDA FOIA regulations are also applicable to this denial.

- 45 C.F.R. § 5.31(g)(1), protects records or information compiled for law enforcement purposes, to the extent that the production of such records could reasonably be expected to interfere with enforcement proceedings.
- 21 C.F.R. § 20.64(a)(1) , which allows us to withhold from public disclosure records or information compiled for law enforcement purposes to the extent that the disclosure of such information could reasonably be expected to interfere with enforcement proceedings.

In determining to withhold such information, FDA considered 5 USC § 552(a)(8)(i), when applicable, and whether FDA reasonably foresees that disclosure of such information would harm an interest protected by the relevant exemption(s) and whether disclosure is prohibited by law.

In accordance with 45 C.F.R. § 5.61 and 21 CFR § 20.41(b)(5), you have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision. Your appeal should clearly identify the agency determination that is being appealed. It would be helpful if you provide specific reasons explaining why you believe the agency's adverse determination should be reconsidered. Your appeal must be mailed or emailed within 90 calendar days from the date of this response, to:

U.S. Food and Drug Administration
5630 Fishers Lane, Room 1035
Rockville, MD 20857
www.fda.gov

Director, Office of The Executive Secretariat
US Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, Md 20857
E-mail FDAFOIA@fda.hhs.gov

Please clearly mark both envelope and your letter "FDA Freedom of information Act Appeal" and reference request number **2024-4099**. Items arriving or delivered after 5 p.m. Eastern Time will be deemed received on the next workday.

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact Charis Wilson at 240-402-9116. You may also contact the FDA FOIA Public Liaison for assistance at: Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is as follows:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road–OGIS
College Park, MD 20740-6001
Telephone at 202-741-5770
Toll free 1-877-684-6448
Facsimile 202-741-5769
E-mail at ogis@nara.gov.

Sincerely yours,

Sarah B. Kotler -S Digitally signed by Sarah B. Kotler -S
Date: 2024.05.15 15:52:01 -04'00'

Sarah Kotler
Director
Division of Freedom of Information