UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PROTECT THE PUBLIC'S TRUST 712 H Street, N.E. Suite 1682 Washington, D.C. 20002, Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION 10903 New Hampshire Avenue. Silver Spring, MD 20993 Defendant.	)	Civil Case No. 1:23-cv-02378

COMPLAINT

1. Plaintiff Protect the Public's Trust brings this action against the U.S. Food and Drug Administration under the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"), seeking relief to compel compliance with the requirements of FOIA.

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 is proper in this Court pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(e).

PARTIES

4. Plaintiff Protect the Public's Trust ("PPT") is a nonprofit corporation dedicated to restoring public trust in government by promoting the fair and equal application of the rules and standards of ethical conduct to all public servants. Consistent with Justice Brandeis's aphorism that "Sunlight is said to be the best of disinfectants; electric light the most efficient policeman," PPT seeks to promote transparency and broadly disseminate

information so that the American people can evaluate the integrity and ethical conduct of those who act in their name. Louis Brandeis, OTHER PEOPLE'S MONEY AND HOW BANKERS USE IT (1914), https://louisville.edu/law/library/special-collections/the-louis-d.-brandeis-collection/other-peoples-money-chapter-v.

5. Defendant U.S. Food and Drug Administration ("FDA") is a federal agency within the meaning of FOIA, 5 U.S.C. § 552(f)(1). FDA has possession, custody, and control of records responsive to PPT's FOIA request.

STATEMENT OF FACTS

6. As Attorney General Garland has made clear, FOIA is "a vital tool for ensuring transparency, accessibility, and accountability in government" whose "'basic purpose . . . is to ensure an informed citizenry,' which is 'vital to the functioning of a democratic society [and] needed to check against corruption and to hold the governors accountable to the governed.'" Merrick Garland, *Memorandum for Heads of Executive Departments and Agencies: Freedom of Information Act Guidelines*, 1 (Mar. 15, 2022) (quoting *Nat'l Labor Rels. Bd. v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 242 (1978)) ("Garland Memo").

I. FOIA Request Control # 2023-3161

7. On or about April 17, 2023, PPT submitted a FOIA request (attached as Exhibit A) to FDA seeking the following:

> From January 1, 2020, through April 12, 2023, records of communications between the identified special interest groups, also referred to as patient and consumer advocacy groups, and the list of FDA officials pertaining to those groups' input on proposed Animal Drug User Fee and Animal Generic Drug User Fee commitments.
>
> Center for Veterinary Medicine Officials:
> a) Director Tracey Forfa, JD
> b) Associate Director Roxanne Schweitzer
> c) Director Matthew Lucia, DVM
> d) Director, Timothy Schell, PhD

e) Director Regina Tan, DVM, MS
f) Director Dorothy Bailey, DVM (Acting)

Organizations:

1. Animal Equality
2. Animal Legal Defense Fund (ALDF)
3. Animal Liberation Front (ALF)
4. Animal Rights National Conference
5. The Animal Welfare Institute (AWI)
6. The Animal Welfare League (AWL)
7. Center for Biological Diversity (CBD)
8. Compassion in World Farming (CIWF)
9. Farm Sanctuary
10. Humane Research Council (HRC)
11. Humane Society of the United States (HSUS)
12. In Defense of Animals (IDA)
13. International Fund for Animal Welfare (IFAW)
14. The Jane Goodall Institute
15. Mercy for Animals
16. The Nonhuman Rights Project
17. People for the Ethical Treatment of Animals (PETA)
18. Physicians Committee for Responsible Medicine (PCRM)
19. Sea Shepherd Conservation Society
20. The Wildlife Conservation Society (WCS)

8. The release of these documents is in the public interest because they will help the public understand the process of advocacy group input associated with FDA user fees on proposed Animal Drug User Fee and Animal Generic Drug User commitments, including from animal drug product user fees. Animal Drugs and Feeds user fees are anticipated to total $58 million in FY2023. *See* Congressional Research Service, *The Food and Drug Administration (FDA) Budget: Fact Sheet* at 5 (Dec. 9, 2022), https://crsreports.congress.gov/product/pdf/R/R44576. The records sought by this request will promote transparency of such fee programs including FDA's user fee negotiations. United States Food and Drug Administration, *FDA: User Fees Explained* (Oct. 3, 2022), https://www.fda.gov/industry/fda-user-fee-programs/fda-user-fees-explained.

9. On April 19, 2023, PPT received an email entitled, "FDA Receipt of FOIA Request Control # 2023-3161," including an Acknowledgement Letter.

10. In its Acknowledgement Letter, FDA indicated "[w]e will respond as soon as possible" but "[d]ue to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA."

11. On May 12, 2023, having received no update on FOIA Request Control # 2023-3161, PPT contacted FDA and inquired, "[p]lease also provide any updates you may have on the search process."

12. On June 5, 2023, the FDA responded indicating only that PPT's request "is pending with our Center for Veterinary Medicine."

13. As the Garland Memo makes clear, "Timely disclosure of records is also essential to the core purpose of FOIA." Garland Memo, at 3.

14. As the record described above indicates, more than 115 days have elapsed since the FDA acknowledged receipt of PPT's request.

15. Yet the FDA still has not made a determination of whether it will comply with PPT's request. *See Citizens for Responsibility and Ethics in Washington v. Fed. Election Comm'n*, 711 F.3d 180 (D.C. Cir. 2013). The FDA has not produced responsive documents to PPT, has not communicated to PPT the scope of the documents it intends to produce and withhold, along with the reasons for such withholding, and has not informed PPT of its ability to appeal any adverse portion of its determination.

16. Through the FDA's failure to make a determination within the time period required by law, PPT has constructively exhausted its administrative remedies and seeks immediate judicial review.

II. FOIA Request Control # 2023-3162

17. On or about April 17, 2023, PPT submitted a FOIA request (attached as Exhibit B) to FDA seeking the following:

> From January 1, 2020, through April 12, 2023, records of communications between the identified special interest groups, also referred to as patient and consumer advocacy groups, and the list of FDA officials pertaining to those groups' input on proposed tobacco user fee commitments.
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> Center for Tobacco Products officials:
> a) Director, Dr. Brian King
> b) Deputy Director, Michele Mital
> c) Janelle R. Barth
> d) Kathleen Crosby
> e) Matthew Farrelly, Ph.D.
> f) May Nelson
> g) Ann Simoneau
>
> Organizations:
> 1. Bloomberg Philanthropies
> 2. Bloomberg Initiative to Reduce Tobacco Use
> 3. Bill and Melinda Gates Foundation
> 4. Bureau of Investigative Journalism
> 5. CDC Foundation
> 6. Global Centre for Good Governance in Tobacco Control
> 7. International Union Against Tuberculosis and Lung Disease
> 8. Johns Hopkins University Bloomberg School of Public Health
> 9. New Venture Fund
> 10. Stopping Tobacco Organization and Products (STOP)
> 11. Vital Strategies
> 12. University of Bath
> 13. University of Illinois at Chicago
> 14. World Health Organization Tobacco-Free Initiative

18. The release of these documents is in the public interest because they will help the public understand the process of advocacy group input associated with FDA user fees from

manufacturers and importers of tobacco products. User fees from manufacturers and importers of tobacco products are anticipated to total $677 million in FY2023. *See* Congressional Research Service, *The Food and Drug Administration (FDA) Budget: Fact Sheet* at 5 (Dec. 9, 2022), https://crsreports.congress.gov/product/pdf/R/R44576. The records sought by this request will promote transparency of such fee programs including FDA's user fee negotiations.

19. On April 19, 2023, PPT received an email entitled, "FDA Receipt of FOIA Request Control # 2023-3162," including an Acknowledgement Letter.

20. In its Acknowledgement Letter, FDA indicated "[w]e will respond as soon as possible" but "[d]ue to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA."

21. On May 12, 2023, having received no update on FOIA Request Control # 2023-3162, PPT contacted FDA and inquired, "[p]lease also provide any updates you may have on the search process."

22. On June 5, 2023, FDA responded, indicating only that PPT's request, along with three other PPT requests, is "pending without our Center for Tobacco Products."

23. As the Garland Memo makes clear, "Timely disclosure of records is also essential to the core purpose of FOIA." Garland Memo, at 3.

24. As the record described above indicates, more than 115 days have elapsed since the FDA acknowledged receipt of PPT's request.

25. Yet the FDA still has not made a determination of whether it will comply with PPT's request. *See Citizens for Responsibility and Ethics in Washington v. Fed. Election Comm'n*,

711 F.3d 180 (D.C. Cir. 2013). The FDA has not produced responsive documents to PPT, has not communicated to PPT the scope of the documents it intends to produce and withhold, along with the reasons for such withholding, and has not informed PPT of its ability to appeal any adverse portion of its determination.

26. Through the FDA's failure to make a determination within the time period required by law, PPT has constructively exhausted its administrative remedies and seeks immediate judicial review.

COUNT I
Violation of FOIA, 5 U.S.C. § 552
Wrongful Withholding of Non-Exempt Responsive Records in Response to FOIA Request Control # 2023-3161

27. PPT repeats and incorporates by reference each of the foregoing paragraphs as if fully set forth herein.
28. PPT properly requested records within the possession, custody, and control of FDA.
29. FDA is an agency subject to FOIA, and therefore has an obligation to release any non-exempt records and provide a lawful reason for withholding any materials in response to a proper FOIA request.
30. FDA is wrongfully withholding non-exempt agency records requested by PPT in FOIA Request Control # 2023-3161 by failing to produce non-exempt records responsive to its request.
31. FDA is wrongfully withholding non-exempt agency records requested by PPT in FOIA Request Control # 2023-3161 by failing to segregate exempt information in otherwise non-exempt records responsive to the request.
32. FDA's failure to provide all non-exempt responsive records violates FOIA.

33. Plaintiff PPT is therefore entitled to relief requiring Defendant FDA to promptly produce all non-exempt records responsive to FOIA Request Control # 2023-3161 and provide indexes justifying the withholding of any responsive records withheld under claim of exemption.

COUNT II
Violation of FOIA, 5 U.S.C. § 552
Wrongful Withholding of Non-Exempt Responsive Records in Response to FOIA Request Control # 2023-3162

34. PPT repeats and incorporates by reference each of the foregoing paragraphs as if fully set forth herein.

35. PPT properly requested records within the possession, custody, and control of FDA.

36. FDA is an agency subject to FOIA, and therefore has an obligation to release any non-exempt records and provide a lawful reason for withholding any materials in response to a proper FOIA request.

37. FDA is wrongfully withholding non-exempt agency records requested by PPT in FOIA Request Control # 2023-3162 by failing to produce non-exempt records responsive to its request.

38. FDA is wrongfully withholding non-exempt agency records requested by PPT in FOIA Request Control # 2023-3162 by failing to segregate exempt information in otherwise non-exempt records responsive to the request.

39. FDA's failure to provide all non-exempt responsive records violates FOIA.

40. Plaintiff PPT is therefore entitled to relief requiring Defendant FDA to promptly produce all non-exempt records responsive to FOIA Request Control # 2023-3162 and provide indexes justifying the withholding of any responsive records withheld under claim of exemption.

REQUESTED RELIEF

Protect the Public's Trust respectfully requests this Court:

(1) Assume jurisdiction in this matter and maintain jurisdiction until the Defendant complies with the requirements of FOIA and any and all orders of this Court.

(2) Order Defendant to produce, within ten days of the Court's order, or by other such date as the Court deems appropriate, any and all non-exempt records responsive to PPT's FOIA Request Control # 2023-3161 and FOIA Request Control # 2023-3162 and indexes justifying the withholding of all or part of any responsive records withheld under claim of exemption.

(3) Enjoin the Defendant from continuing to withhold any and all non-exempt records responsive to PPT's FOIA Request Control # 2023-3161 and FOIA Request Control # 2023-3162.

(4) Award PPT the costs of this proceeding, including reasonable attorney's fees and other litigation costs reasonably incurred in this action, pursuant to 5 U.S.C. § 552(a)(4)(E).

(5) Grant PPT other such relief as the Court deems just and proper.

Dated: August 16, 2023

Respectfully submitted,

PROTECT THE PUBLIC'S TRUST
By Counsel:

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