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BEFORE THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

COMPLAINT FOR INJUNCTIVE, DECLARATORY, AND OTHER RELIEF

FREEDOM OF INFORMATION ACT

MARK BAKER,

Plaintiff,

vs.

UNITED STATES FOOD AND DRUG ADMINISTRATION

Defendant.

Case No.: 2:25-CV-250-DAD-CKD (PS)

Plaintiff Mark Baker ("Plaintiff"), brings this action against defendant U.S. Food and Drug Administration ("FDA"), and alleges as follows:

I. INTRODUCTION

1. On August 17, 2022, Plaintiff served a request under the Freedom of Information Act ("FOIA") on the FDA for information related to the FDA's decisions involving the testing, evaluation, and regulation of Light Emitting Diode ("LED") products. On September 23, 2024, Plaintiff filed a lawsuit against the FDA and co-defendant the National Highway Traffic Safety Administration, for failing to establish and maintain a liaison to test and evaluate LED vehicle headlamps are required by 21 U.S.C. 360ii(a)(6)(A). On September 27, 2024, just four days after the filing of Plaintiff's lawsuit, but over two years after Plaintiff's FOIA request, the FDA responded to Plaintiff's FOIA request by providing a single 19-page document, despite the known existence of many more documents, likely in the hundreds.

2. On September 27, 2024, Plaintiff appealed the FDA's FOIA release and stated, "I am requesting a prompt response as to why the FDA has chosen to not provide me the information that I have requested and the legal justification for not providing that information." The FDA did not respond.

3. On January 11, 2025, Plaintiff requested a Meet and Confer with DOJ attorney Scott Kennedy, who is representing the FDA in Plaintiff's lawsuit, and Michael Jenack, Government Information Specialist at the FDA Center for Devices and Radiological Health ("CDRH"). On January 14, 2025, Mr. Kennedy responded that the government refused to Meet and Confer. On January 14, 2025, Plaintiff notified the FDA that Plaintiff has exhausted all administrative remedies and of Plaintiff's intent to sue.

II. PARTIES

4. Plaintiff is Mark Baker, a citizen of the United States of America, and resident of California.

5. Defendant FDA is an agency of the federal government within the United States Department of Health and Human Services (HHS). The Secretary of HHS has delegated to the FDA the authority to administer the provisions of the Radiation Control for Health and Safety Act for the regulation of electronic products the emit electromagnetic radiation. FDA's headquarters is located at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

III. JURISDICTION AND VENUE

6. This Court has jurisdiction over this action pursuant to 5 U.S.C. §552(a)(4)(B) and 28 U.S.C. § 1331 and may grant declaratory relief pursuant to 28 U.S.C. §§ 2201 and 2202.

7. Venue is proper in this District pursuant to 5 U.S.C. § 552(a)(4)(B) because Plaintiff lives in this District. Note: Plaintiff's mailing address is not in this district.

8. Because the Department has failed to comply with the applicable time-limit provisions of FOIA, Plaintiff is deemed to have exhausted its administrative remedies pursuant to 5 U.S.C. § 552(a)(6)(C)(i) and is now entitled to the requested relief from this Court.

IV. FACTS

A. The Attorney General's FOIA Disclosure Directive

9. In a March 15, 2022, directive to executive departments and agencies (including the FDA), Attorney General Merrick Garland emphasized that FOIA's "'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.'" Memorandum for Heads of Executive Departments and Agencies: Freedom of Information Act Guidelines, Memo Att'y Gen (2022), https://rb.gy/znu3f (quoting NLRB v. Robbins Tire & Rubber Co.,437 U.S. 214, 242 (1978)) ("Garland Directive").

10. The Garland Directive emphasized the "Presumption of Openness" required of federal departments and agencies, including the Department, noting that responsive records may only

be withheld “if: (1) the agency reasonably foresees that disclosure would harm an interest protected by one of the nine exemptions that FOIA enumerates; or (2) disclosure is prohibited by law. 5 U.S.C. § 552(a)(8)(A)(i).” Id. at 1. Attorney General Garland warned agencies that requested “[i]nformation that might technically fall within an exemption should not be withheld from a FOIA requester unless the agency can identify a foreseeable harm or legal bar to disclosure” and that“[i]n case of doubt, openness should prevail.” Id. Attorney General Garland instructed further that pursuant to 5 U.S.C. § 552(a)(8)(A)(ii), when “an agency determines that it cannot make full disclosure of a requested record, FOIA requires that it ‘consider whether partial disclosure of information is possible’ and ‘take reasonable steps necessary to segregate and release nonexempt information.’” Id.

B. Plaintiff’s FOIA Request

11. On August 12, 2022, Plaintiff wrote to the Ombudsman, Office of Regulatory Affairs, Food and Drug Administration, requesting to know when the FDA will publish performance standards for LED products as required by the 1968 Radiation Control for Health and Safety Act. On August 16, 2022, the FDA responded by falsely claiming, “LED products/lights are not subject to performance standards and do not require annual reporting” (EXHIBIT A).

12. On August 16, 2022, Plaintiff submitted a FOIA request to the FDA, stating "Congress directed the FDA to regulate electromagnetic radiation from electronic devices in 1968. The FDA claims that they are not required to regulate electromagnetic radiation from products containing Light Emitting Diodes and that the FDA is unaware of any negative health effects from LED light. We therefore request the data that the FDA uses to draw the conclusion that it is not mandated to regulate electromagnetic radiation from LED products and the data that the FDA uses to conclude that there are no negative health effects, including impacts on the eye and nerves, from LED light." The FDA assigned confirmation number FDA22085814 to this FOIA request.

13. On August 17, 2022, the FDA sent a letter to Plaintiff acknowledging Plaintiff's FOIA request and assigning FOIA Control Number 2022-6020. (EXHIBIT B).

14. On December 15, 2022, Plaintiff submitted a second FOIA request to via the FDA's website, stating, "The Radiation Control for Health and Safety Act passed on October 18, 1968, and yet the FDA still has not published regulations for Light Emitting Diodes. This request is for all records showing discussions within the FDA about regulation of LEDs, including meeting notes, emails, and petitions that provide insight as to why the FDA has not regulated LEDs. Our petition to the FDA to regulate LED products was submitted on June 15, 2022, and yet still there has been no decision by the FDA. This FOIA requests all meeting notes, emails, and phone calls showing who FDA staff has contacted about our petition, including any discussions with the FDA Commissioner, any discussions with other federal agencies, and any discussions with lighting or automotive companies." (Exhibit C).

15. On February 13, 2023, the FDA responded to Plaintiff's December 15, 2022, FOIA request by assigning FOIA Control Number 2022-8833, and stating that the FDA Office of Chief Counsel was unable to locate any records, and that case 2022-8833 was closed. (EXHBIT D).

16. On February 14, 2023, Plaintiff contacted the Health and Human Services Office of Inspector General and was informed that the February 13, 2023, letter was strictly from the Office of Chief Counsel and that the letter did not apply to other departments within the FDA. However, the OIG did not explain why the entire case 2022-8833 was closed.

17. On March 5, 2023, Plaintiff contacted the FDA FOIA Public Liaison and requested to know why the FOIA documents have not been delivered. (Exhibit E).

18. On March 6, 2023, Plaintiff followed up with a second letter to the FDA FOIA Public liaison with additional information and again requesting the FOIA documents (Exhibit F). On March 6, 2023, the FDA Denial & Appeals Officer, Claris Wilson, notified Plaintiff that the "no records" response was from the FOIA OCC office only, and was not a final agency response. Ms. Wilson did not explain why case 2022-8833 was closed if it was not a final agency response. (Exhibit G).

19. On March 7, 2023, Plaintiff submitted a FOIA appeal. (Exhibit H). On March 7, 2023, Ms. Wilson notified Plaintiff that case 2022-8833 was still open, despite the letter from the FDA OCC that the case was closed. (Exhibit I).

20. On March 9, 2023, Ms. Wilson notified Plaintiff that this case was placed into "unusual circumstances" and was assigned a tracking number of 23-0024AA. (Exhibit J).

21. On March 10, 2023, the Ms. Wilson notified Plaintiff that Plaintiff's FOIA appeal was denied, stating, "Health and Human Services (HHS) FOIA regulations, specifically 45 CFR § 5.61 provides a right to appeal only after an adverse determination by FDA. As no adverse determination has yet been made, there is no action for this office to consider under appeal." (Exhibit K).

22. On April 10, 2023, Plaintiff submitted a letter to the FDA FOIA Public Liaison requesting an update on Plaintiff's FOIA request 2022-8833. (Exhibit L). The FDA FOIA Public Liaison did not respond.

23. On May 24, 2024, in a 19-page letter, the FDA denied all four Soft Lights Foundation petitions to the FDA to comply with 21 U.S.C. 360ii for LED products. (Exhibit M).

24. On September 23, 2024, Plaintiff filed a lawsuit against the FDA and NHTSA for essentially dissolving TEPRSSC and for failing to comply with 21 U.S.C. 360ii(a)(6)(A) and establish and maintain a liaison to test and evaluate LED headlamps.

25. On September 27, 2024, the FDA FOIA Office responded to FOIA request 2022-6020 by providing a single document. That single document is the 19-page denial letter of the four Soft Lights Foundation petitions to the FDA to regulate various LED products. No other documents were provided. (Exhibit N).

26. On September 27, 2024, Plaintiff filed an appeal with Michael Jenack of the FDA FOIA Office, requesting an explanation of why only a single document was provided. (Exhibit O). The FDA FOIA office did not respond.

27. Plaintiff has now exhausted all administrative remedies and seeks immediate judicial review in this matter.

C. Bad Faith Actions by FDA

28. The FDA's actions related to Plaintiff's two FOIA requests bear no resemblance to the openness and transparency referred to in the Attorney General's letter to FDA staff.

29. Plaintiff's FOIA request for documents related to decision making for LED products was submitted on August 16, 2022. After a 2-year wait, the only document that the FDA produced was the 19-page denial letter of the four Soft Lights Foundation petitions which was issued on May 24, 2024. This means that Plaintiff waited for 2 years for the FDA FOIA Office to produce a document that didn't even exist when Plaintiff filed the FOIA request. Thus, rather than providing the documents that existed at the time of Plaintiff's FOIA request, the FDA waited for nearly 2 years to create a *post-hoc* rationalization for why the FDA was not complying with 21 U.S.C. 360ii for LED products. This is a dishonest, bad faith action by the FDA.

D. Known Records at the FDA

30. The FDA unlawfully withheld documents that are known by Plaintiff to exist or that should have been created.

a) 2016 TEPRSSC Meeting Minutes and Transcript[1] which discusses publishing performance standards for LED products. Despite these minutes, the FDA claims that it is not considering performance standards for LED products.

b) TEPRSSC Charter which states that TEPRSSC should meet every other year.[2] Despite this charter, TEPRSSC has met only once in the past 21 years.

c) Meeting minutes, notes, or any document showing that the FDA and the National Highway Traffic Safety Administration ("NHTSA") discussed the 21 U.S.C. 360ii(a)(6)(A) requirement to meet and liaison to test and evaluate LED headlights. There should exist

[1] https://public4.pagefreezer.com/browse/FDA/12-01-2022T02:57/https://www.fda.gov/advisory-committees/technical-electronic-product-radiation-safety-standards-committee/2016-meeting-materials-technical-electronic-product-radiation-safety-standards-committee

[2] https://www.fda.gov/advisory-committees/technical-electronic-product-radiation-safety-standards-committee/charter-technical-electronic-product-radiation-safety-standards-committee

a record justifying the FDA and NHTSA's decision to not test and evaluate LED headlights, especially considering that over 68,000 individuals have submitted signatures and comments to the FDA and NHTSA detailing the significant adverse health and safety impacts of LED headlights.

d) Meeting minutes, notes, or any document showing how the FDA decided to ignore the requirements of the Federal Advisory Committee Act ("FACA") by not allowing the Congressionally mandated TEPRSSC to evaluate the four Soft Lights Foundation petitions and to instead use an undisclosed third-party outside agency that is not FACA-compliant.

e) The petition comments from the public petition to ban blinding headlights which has been submitted to both the FDA and NHTSA multiple times.[3]

f) The LED Incident Reports which have been submitted by the Soft Lights Foundation to the FDA monthly.[4]

g) FDA Accidental Radiation Occurrence Reports for LED products.[5]

h) The documents that the third-party outside agency used to recommend denial of the four Soft Lights Foundation petitions to the FDA to comply with 21 U.S.C. 360ii for LED products, the qualifications of the outside agency and its staff, and any reports created by the outside agency.

i) Meeting minutes, notes, or any document justifying how the FDA decided not to comply with 21 U.S.C. 360ii(a)(6)(A) and establish and maintain a liaison with NHTSA, DOT, EPA, CPSC, OSHA, Access Board, FAA, DOE, FHWA, and all other federal agencies to test and evaluate LED products such as LED headlights, LED streetlights, LED General Service Lamps, LED strip lights, LED indicator lights, LED flashing lights, LED displays, LED bicycle

[3] https://www.change.org/p/u-s-dot-ban-blinding-headlights-and-save-lives
[4] https://www.softlights.org/led-incident-reports/
[5] https://www.fda.gov/radiation-emitting-products/getting-radiation-emitting-product-market-frequently-asked-questions/submitting-reports-and-requirements-maintaining-records-radiation

lights, LED lights on children's toys, or any other LED product to ensure that these products do not cause harm to human health or create a safety hazard.

j) Documents and records related to testing and evaluating LED products.

V. FIRST CAUSE OF ACTION

Violation of FOIA, 5 U.S.C. § 552
(Wrongful Withholding by the Department of Non-Exempt Records Responsive to FOIA Request)

31. The Plaintiff realleges and incorporates by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

32. Through its two FOIA Requests, Plaintiff properly requested records within the possession, custody, and control of the FDA.

33. The FDA is a federal agency subject to FOIA's statutory provisions and is obligated to provide, in a timely manner, all non-exempt records responsive to Plaintiff's FOIA Request. In the event that the FDA withholds any responsive records, it must provide a lawful reason for withholding those records in response to a FOIA request.

34. After the passage of 887 days, the FDA has provided no such lawful reason for withholding responsive records and has demonstrably ignored Plaintiff's FOIA Requests, the FDA's statutory obligations under FOIA, and the Garland Directive.

35. By failing to provide non-exempt records responsive to Plaintiff's FOIA Requests, the FDA is wrongfully withholding agency records lawfully requested by Plaintiff in violation of the FDA's statutory FOIA obligations.

36. Plaintiff is thus entitled to declaratory and injunctive relief requiring the FDA to produce promptly any and all records responsive to its FOIA Request.

VI. RELIEF REQUESTED

37. Therefore, Plaintiff requests that the Court:

a) Assume jurisdiction in this matter and maintain jurisdiction until the FDA complies with its statutory FOIA production obligations and any and all orders of this Court;

b) Declare the FDA in violation of FOIA and order it to conduct immediately a records search or searches reasonably calculated to identify all records responsive to Plaintiff's FOIA Requests;

c) Order the FDA to produce, within twenty days of the Court's order or by other such date as the Court deems appropriate, any and all records responsive to Plaintiff's FOIA Requests, including those documents identified in Title IV, Section D in this claim;

d) Order the FDA to produce, within twenty days of the Court's order or by other such date as the Court deems appropriate, a Vaughn Index of any documents that are withheld under 5 U.S.C. § 552(b)(5).

e) Enjoin the FDA from continuing to withhold any and all non-exempt records responsive to Plaintiff's FOIA Requests;

f) Award Plaintiff his fees, costs, disbursements and expenses, including reasonable attorney's fees and other litigation costs reasonably incurred in this action, pursuant to 5 U.S.C. § 552(a)(4)(E)(i); and

g) Grant Plaintiff equitable and such other relief as this Court may deem just and proper

Dated: January 20, 2025

Respectfully submitted,

/s/ Mark Baker
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