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234-206-1977
Pro Se

THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

SACRAMENTO DIVISION

MARK BAKER,

Plaintiff,

vs.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendant

Case No.: 2:25-cv-0250-DAD-CKD (PS)

PLAINTIFF RESPONSE TO DEFENDANT'S MOTION TO DISMISS COMPLAINT FOR LACK OF SUBJECT MATTER JURISDICTION

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I. INTRODUCTION

Plaintiff, Mark Baker, is a private citizen of the United States of America and the Founder and President of the Soft Lights Foundation, a 501(c)(3) non-profit corporation registered in the state of Oregon. Plaintiff receives mail through a commercial mail scanning facility at 9450 SW Gemini Drive PMB 44671, Beaverton, OR 97008. Mail addressed to the Soft Lights Foundation is received at the same address. Plaintiff lives in the state of California, within the geographical area covered by the United States District Court Eastern District of California. Plaintiff is not authorized to file court documents through PACER, and therefore physically files documents with the clerk at the Robert T. Matsui Federal Courthouse in Sacramento, California.

Plaintiff routinely submits formal regulatory petitions and FOIA requests to the United States government with Soft Lights Foundation letterhead, and a signature line with the name Mark Baker, who is listed as the President of the Soft Lights Foundation. However, there has been no delineation in these filings as to whether the filing is made solely on behalf of the Soft Lights Foundation, or if the Mark Baker signature also includes Mr. Baker as a private citizen. The submissions are thus ambiguous regarding whether Mark Baker, the individual, is requesting FOIA information, whether the Soft Lights Foundation is requesting FOIA information, or whether both the individual and the Soft Lights Foundation are requesting FOIA information.

In the case of this lawsuit, the Plaintiff is Mark Baker, an individual. Mr. Baker may not file a lawsuit on behalf of the Soft Lights Foundation because Mr. Baker is not licensed to practice law and thus may not represent clients. This lawsuit is filed Pro Se. However,

supporters of the Soft Lights Foundation will benefit from a positive outcome of this lawsuit and the release of FDA records related to LED lights.

As detailed below, the question of whether the FOIA was filed by Mark Baker, an individual, or Mark Baker, President of the Soft Lights Foundation, is irrelevant.

II. ARGUMENTS

The text of the FOIA request from Plaintiff Mark Baker dated December 15, 2022, states, "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 A).

The text of the FOIA request does not state that the Soft Lights Foundation is making the FOIA request, nor does the FOIA request state that Mark Baker, an individual, is making the FOIA request. It is ambiguous, and irrelevant, as to whether Mark Baker is acting on his own behalf, as President of the Soft Lights Foundation, or both.

In the letter from the FDA dated February 13, 2023, the FDA wrote, "After a diligent search of our files, the Office of the Chief Counsel (OCC) of the Food and Drug

Administration was unable to locate any records responsive to your request". (EXHIBIT B). The use of the pronoun "your" appears to indicate that the FDA believes that the FOIA request is from Mark Baker, an individual. If the FDA had believed that the request was from the Soft Lights Foundation, the FDA would have written, "[T]he Food and Drug Administration was unable to locate any records in response to the Soft Lights Foundation's request." However, it is irrelevant whether the FDA was considering the request as from Mark Baker, an individual, or from the Soft Lights Foundation, as the documents would have been delivered to Mark Baker in either case.

In the appeal to the FDA dated March 7, 2023, Mark Baker wrote, "This letter is in response to your letter to me dated March 6, 2023, and my appeal of my FOIA request for FDA documents." (EXHIBIT C). Here, the language reasonably suggests that the FOIA requested was submitted by Mark Baker, an individual, because if the petition had been submitted on behalf of the Soft Lights Foundation, the sentence would have read, "…the Soft Lights Foundation appeal of the Soft Lights Foundation FOIA request…", instead of "…my appeal of my FOIA request…" Nor did the FDA object to this language indicating that Mark Baker, an individual, was appealing. But again, the issue of whether Mark Baker, the individual, or Mark Baker, the President of the Soft Lights Foundation, submitted the FOIA request, is irrelevant.

The Freedom of Information Act (FOIA): A Legal Overview details Congress' intent in passing the Freedom of Information Act.[1] The document states, "Lastly, FOIA directs agencies to disclose nonexempt agency records to "any person" upon request. A 'person' is

[1] https://www.congress.gov/crs-product/R46238

defined as ‘an individual, partnership, corporation, association, or public or private organization other than an agency.’ Courts have held that, along with individuals, organizational entities such as corporations and state and foreign governments have access rights under FOIA”

As described in the paragraph above, essentially any person or any entity is entitled to the information held by a federal agency, which in this case is the US Food and Drug Administration. It is not the intent of Congress to hide information from the public or to make it difficult to request this information from the government. It is therefore unimportant and irrelevant as to whether Mark Baker, an individual, or Mark Baker, President of the Soft Lights Foundation, requested the FOIA information. In either case, the FDA would be releasing the information to the same person: Mark Baker.

In the document titled “FOIA Update: OIP Guidance: Determining the Scope of a FOIA Request”, the US Department of Justice states, “In short, as the Court of Appeals for the D.C. Circuit recently emphasized, agencies should interpret FOIA requests "liberally" when determining which records are responsive to them. *Nation Magazine v. United States Customs Serv.*, No. 94-5275, 1995 WL 722700, at *3 (D.C. Cir. Dec. 8, 1995).” The Conclusion states, “In sum, all federal agencies should go as far as they reasonably can to ensure that they include what requesters want to have included within the scopes of their FOIA requests. Agencies can best do so through liberal interpretations of FOIA requests and by limiting their use of document "scoping" to only those instances that are justified by its underlying considerations. In all instances, the key consideration is the need for full and open communication with the FOIA requester, so that the requester can make a fully

informed decision about any document "scoping" as part of the agency's administrative process."

The Supreme Court stated, "As a general rule, withholding information under FOIA cannot be predicated on the identity of the requester." (National Archives and Records Administration v. Favish, 541 U.S. 157 (2004))). Thus, the Supreme Court has already clarified that it doesn't matter whether Mark Baker's identity is an individual or whether Mark Baker's identity is the President of the Soft Lights Foundation. The defendant's support of its Motion to Dismiss this FOIA case fails.

The attempt by the US DOJ to have this FOIA case dismissed due to a perceived jurisdiction issue is directly contradictory to the goals of Congress, the FOIA guidance issued by the DOJ, and Supreme Court decisions.

There is no benefit to the government in denying access to these public records due to a perceived jurisdictional issue. Both Mark Baker, the individual, and Mark Baker, the President of the Soft Lights Foundation, could simply submit another FOIA request which unambiguously clarifies the nature of the requester's status. The FDA would then be required to release the documents that were requested, and the only accomplishment of a sustained Motion to Dismiss for this case would be extra paperwork and labor by the government and delayed justice for the public.

III. CONCLUSION

Based on foregoing, Plaintiff respectfully requests that the Court deny the defendant's Motion to Dismiss.

Dated: March 30, 2025

Respectfully Submitted,

By: /s/ Mark Baker
In Pro Per

Gmail

Mark Baker <mbaker@softlights.org>

FDA FOIA

Mark Baker <mbaker@softlights.org> Thu, Dec 15, 2022 at 2:16 PM
To: Mark Baker <mbaker@softlights.org>

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 B

U.S. FOOD & DRUG ADMINISTRATION

February 13, 2023

Mark Baker
Soft Lights Foundation
9450 SW Gemini Drive, PMB 44671
Beaverton, OR 97008
EMAIL: mbaker@softlights.org

Dear Mr. Baker,

After a diligent search of our files, the Office of the Chief Counsel (OCC) of the Food and Drug Administration was unable to locate any records responsive to your request #2022-8833 dated 12/16/22 requesting 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, as well as all meeting notes, emails, and phone calls showing who FDA staff has contacted about our June 15, 2022 petition, including any discussions with the FDA Commissioner, any discussions with other federal agencies, and any discussions with lighting or automotive companies.

OCC considers your request closed. Please be advised that your request may have been submitted to one or more other component offices within FDA. This office(s) will respond to your request separately.

This is not the agency's final response, and you will receive additional appeal rights with the final response, so you do not have to act at this time.

If you have any questions about this response, you may contact Lakita Stephens at 301-796-0661 or at Lakita.Stephens@fda.hhs.gov.

Sincerely,

David Mednick -S
Digitally signed by David Mednick -S
Date: 2023.02.13 09:56:44 -05'00'

David Mednick
Deputy Chief Counsel

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

Exhibit C

Soft Lights Foundation

9450 SW Gemini Drive
PMB 44671
Beaverton, OR 97008

March 7, 2023

BY EMAIL

Charis Wilson, Denials and Appeals Officer
FOIA, Food and Drug Administration
Appeal File: 23-0023AA
fdafoia@fda.hhs.gov

Re: FOIA Request for Documents Related to Light Emitting Diode Regulations

Dear Charis Wilson,

This letter is in response to your letter to me dated March 6, 2023, and my appeal of my FOIA request for FDA documents. I wish to correct error(s) in your letter to ensure that I receive what I am requesting.

My goal, as President of the Soft Lights Foundation, is to provide information to members of Congress and the public surrounding the FDA's decision to not regulate the visible radiation emitted by Light Emitting Diode products. The FDA is mandated by the 1968 Radiation Control for Health and Safety Act to publish Performance Standards for LED products, and the FDA acknowledges this requirement. Yet, despite 50+ years of time passing since the Congressional mandate, the FDA has not published any performance standards for the visible radiation emitted by LED products.

The result of FDA's failure to publish Performance Standards for LED products is that an astonishing number of products are now in service, consisting of LED vehicle headlights, LED street lights, LED General Service Lamps, LED strobe lights, LED strip lights, LED appliance light indicators, etc. and these LED lights are entirely unregulated. LED visible radiation is extremely powerful and dangerous, causing photosensitive seizures, migraines, panic attacks, impaired vision, and permanent eye injury, and the increase in light pollution has drastically increased the risks of mood disorders, cancers, diabetes, heart disease and many other adverse health impacts.

Every federal agency that I have contacted, including the DOE, NHTSA, FHWA, FAA, OSHA, CPSC, and EPA have deferred to the FDA for regulations for LED products.

I submitted a petition to the FDA on June 12, 2022, to compel the FDA to comply with the 1968 Congressional mandate, and this petition provides proof that LED visible radiation is hazardous to human health: FDA-2022-P-1151. This petition has been acknowledged by the FDA, but otherwise entirely ignored.

In December, 2022, I submitted a FOIA request to the FDA in an attempt to understand why the FDA is not acting on our petition and not taking any action to regulate LED products. On December 16,

2022, I received notice from the FDA that my FOIA request was received, case number: 2022-8833. Since that time, the only response I have received is from the FDA's Office of Chief Counsel, stating that their office as "no records" related to this issue. I find this statement to be astonishing, although possible.

The FDA's Center for Devices and Radiological Health is responsible for regulating electromagnetic radiation from electronic products. However, the CDRH has provided no response to my FOIA requests, and certainly no documents. This purposeful effort by the CDRH to hide the health impacts and lack of regulation of LED products from the public is unacceptable.

My FOIA request is that the FDA provide all records related to this situation. Congress passed the law in 1968. During that entire time, what was the FDA doing in regards to regulation of LED visible radiation? The FDA has published on their website that the Performance Standards for Lighting Emitting Products is 21 CFR Part 1040, and that the performance standards for laser products is 1040.10, and also that LEDs are specifically not regulated under 1040.10. So where are the performance standards for LED products? Where is part 1040.40 Light Emitting Diode Products?

Who made the decision to not regulate LED products? What documents were used to make this decision? How was it decided to not include LED products in the laser product standard? There is a vast amount of epidemiological data related to the adverse health effects caused by LED products, especially blue wavelength light, but also square wave flicker and the spatially non-uniform shape of LED visible radiation. What has the FDA done with all of this data? There are also radiation reports from people suffering radiation poisoning from LED products. What has the FDA done with those reports?

Our petition, FDA-2022-P-1151 was submitted on June 12, 2022. Why has the FDA not approved this petition? Who is the FDA talking to? Has the FDA notified NHTSA, DOE, CPSC, OSHA, etc. that LED products are unvetted and unsafe? Has the FDA notified Congress of this crisis? Does the FDA understand that LED visible radiation is a directed energy beam of spatially non-uniform energy that does not disperse following an inverse square law, thus making this directed energy powerful and dangerous?

I am requesting all the documents from the CDRH and other departments within the FDA that show a complete history of how we arrived at this situation of billions of LED emitters placed into the environment with absolutely no regulations published by the FDA to keep humans and the environment safe. I intend on providing these documents to members of Congress and the media as a public service.

Sincerely,

/s/ Mark Baker
President
Soft Lights Foundation
mbaker@softlights.org