Soft Lights Foundation

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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
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