Mark Baker
9450 SW Gemini Drive PMB 44671
Beaverton, OR 97008
mbaker@softlights.org
Pro Se

THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

SACRAMENTO DIVISION

MARK BAKER,

Plaintiff,

vs.

U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,

Defendants

Case No.: 2:24-CV02558-DJC JDP (PS)

PLAINTIFF RESPONSE TO DEFENDANT'S RESPONSE TO PETITION FOR WRIT OF MANDATE, RULE 26(F).

I. INTRODUCTION

1. Plaintiff agrees that this case is an Administrative Procedure Act ("APA") case and that Rule 26(a)(1)(B) states that an action for review of an administrative record exempts APA proceedings from initial disclosure. However, the Supreme Court has recognized that there is one exception: when the government acts in bad faith. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402 (1971).

2. As per The Scope of Evidentiary Review in Constitutional Challenges to Agency Action in the Chicago Law Review, "The bad faith exception ensures that an insufficient

administrative record does not hinder plaintiffs trying to vindicate their constitutional rights."[1]

3. A government can only properly function if government officials act in good faith. When government officials act dishonestly, withhold evidence, and evade statutes and regulations, the government ceases to properly function.

4. Federal Rules of Civil Procedure Rule 26(a)(1)(B)(i) states, "The following proceedings are exempt from initial disclosure: an action for review on an administrative record." For the Court to be able to review the administrative record, the Court must have the administrative record to review. In this case, the government has dishonestly withheld from the Court the very administrative record that the Court needs to make its reasoned decision. The following examples provide a strong showing of bad faith, dishonest actions by the government in this case.

II. TEPRSSC

5. TEPRSSC has only met once in the past 21 years. The government's argument is that this is perfectly reasonable because TEPRSSC is not required to meet following a specific schedule and because the FDA has not proposed to publish any performance standards for LED products. Yet the government's position is completely debunked by its own documents. The TEPRSSC Charter states that TEPRSSC should meet every other year, and the transcript from the 2016 TEPRSSC meeting states that the FDA is considering performance standards for LED products. However, these are the very two documents that

[1] https://lawreview.uchicago.edu/sites/default/files/Hurst_EvidentiaryReview_88UCLR1511.pdf

were withheld from the Court as the Court attempts to consider Defendant's Motion to Dismiss.

6. The government's actions are the very definition of bad faith. The Cornell Legal Information Institute states, "Bad faith refers to dishonesty or fraud in a transaction. Depending on the exact setting, bad faith may mean a dishonest belief or purpose, untrustworthy performance of duties, neglect of fair dealing standards, or a fraudulent intent. It is often related to a breach of the obligation inherent in all contracts to deal with the other parties in good faith and with fair dealing."

7. The government's actions cannot possibly be honest or acting in good faith or trustworthy when the government withheld from this Court the TEPRSSC Charter document and the 2016 TEPRSSC Transcript that disproves the government's position.

8. The government states, "But nothing in the statute obligates FDA to prevent vacancies in these positions at all times, particularly not when FDA is declining to propose any performance standard." *Memorandum of Points and Authorities in Support of Motion to Dismiss*, Page 18, Line 9. This is another example of bad faith by the government. The 2016 TEPRSSC Transcript proves that the FDA is proposing performance standards for LED products, not declining performance standards for LED products. The government's effort to convince the court that the FDA is declining to publish performance standards, while withholding the 2016 TEPRSSC meeting transcript is dishonest and provides the strong showing of improper behavior by the government that is required to establish the APA exception for discovery requirements.

9. The government states, "Indeed, Plaintiff overlooks that FDA can discharge its duty under § 360kk(f)(1)(A) by ensuring that the Committee stands prepared to consult on a

performance standard whenever FDA is prepared to propose one, just as FDA has done in the past." *Id*. Again, the government is making a bad faith overture to this Court by claiming that that TEPRSSC stands prepared to consult with the FDA on LED performance standards whenever the FDA proposes performance standards, while withholding from this Court the 2016 TEPRSSC transcript proving that the FDA has already proposed performance standards for LED products. The TEPRSSC Charter, the latest of which was signed in December 2022, states that TEPRSSC should meet every two years. It is now December 2024, and not only has TEPRSSC not met in the past two years, TEPRSSC has not met since 2016, has 11 vacancies out of 15, and has no Chairperson. Rather than "stand[ing] prepared" for FDA consultation, TEPRSSC has been effectively dissolved since 2016.

10. During the Meet and Confer, Plaintiff asked Mr. Kennedy if it was his decision to withhold the TEPRSSC Charter and 2016 TEPRSSC Transcript from the Court, or whether the FDA directed Mr. Kennedy to withhold the documents, but Mr. Kennedy refused to state. Either way the government purposely withheld these two documents, and it was not merely an oversight.

11. It is the dishonest withholding of evidence (the TEPRSSC Charter and the 2016 TEPRSSC Transcript) from this Court that proves that the Plaintiff has made a strong showing of bad faith and improper behavior by the government and is thus entitled to discovery information because there is such a strong probability that that the government has withheld additional evidence from this Court and from Plaintiff.

III. SECRET ORGANIATION

12. The government writes, "FDA also 'engaged an independent, third-party organization to conduct a comprehensive literature search to identify the current state of knowledge with regard to adverse health effects of LED light on humans.' *Memorandum of Points and Authorities in Support of Motion to Dismiss*, Page 9, Line 16.

13. Yet the government has withheld from the Court everything about this "third-party organization" that forms the administrative record. The government did not provide the name of this third-party organization, nor the qualifications, nor any of the documents related to LED headlamps that the third-party organization supposedly reviewed.

14. The government also withheld from the Court the justification for how the FDA decided to use a secret outside organization to perform a literature review, when Congress mandates that TEPRSSC be involved in this action. The FDA is considering performance standards for LED products, as documented in the 2016 TEPRSSC Transcript, so how does the FDA justify bypassing TEPRSSC? How can the Court review the administrative record when the government acts in bad faith and withholds the very documents that the Court needs to understand whether the FDA is engaged in reasoned decision making?

15. The use of a secret organization to perform a literature review rather than using the TEPRSSC is dishonest, and the government's decision to withhold from the Court the administrative documents that show how the FDA decided to use the third-party organization serves to reinforce that the government is acting in bad faith.

IV. FDA AND NHTSA LIAISON

16. In the government's denial of the four Soft Lights Foundation petitions to the FDA to regulate LED products, the only mention of LED headlamps is in a footnote, "For vehicle headlights, FDA notes the National Highway Traffic Safety Administration (NHTSA)

standard Federal Motor Vehicle Safety Standard (FMVSS) No. 108, Lamps, Reflective Devices, and Associated Equipment (49 CFR 571.108)." Defendant Motion to Dismiss Exhibit 1, Page 12.

17. In the December 2, 2022, letter to the Soft Lights Foundation, NHTSA wrote, "*NHTSA also wants to express appreciation to the Petitioner for bringing to its attention health concerns that the Petitioner associates with LED headlamps. NHTSA takes these concerns seriously. NHTSA, as an agency focused on automotive safety, also recognizes the expertise of its sister agencies that are health-focused, such as the FDA*."

18. The thousands of comments posted on the change.org citizen petition to ban blinding headlights have been submitted to NHTSA and the FDA multiple times.[2] This information forms part of the administrative record. The tens of thousands of signatures and thousands of comments prove that LED headlights are dangerous and defective. Yet the government makes no mention of this information and has withheld these comments from the Court. How did the FDA and NHTSA conclude that a liaison between their two agencies is not justified and how did these agencies conclude that testing and evaluating LED headlamps is unnecessary, given the thousands of reports of harm that have been submitted by the public? How can the Court review the administrative record related to LED headlamps when the government dishonestly withholds this information from the Court?

19. A footnote does not constitute the administrative record. A single sentence by NHTSA, referring to the FDA for health-focused matters, does not constitute the administrative record. Where are the documents showing how the FDA and NHTSA made the decision

[2] https://change.org/p/u-s-dot-ban-blinding-headlights-and-save-lives/

not to establish and maintain a liaison to test and evaluate LED headlamps? The government has withheld these documents from the Court. The Court cannot review the administrative record when the government dishonestly withholds the documents that the court needs to reach its conclusions. The government is acting dishonestly and in bad faith.

V. FREEDOM OF INFORMATION ACT

20. On December 15, 2022, Plaintiff submitted a Freedom of Information Act request to the FDA, stating "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).

21. After nearly two years, on September 26, 2024, three days after Plaintiff filed this lawsuit, the FDA responded to Plaintiff's FOIA request by providing a single document, which was the FDA's May 24, 2024, denial of the four Soft Lights Foundation petitions to regulate LED products.

22. 21 C.F.R. 20.20(a) states, "The Food and Drug Administration (FDA) will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information, and the need for the Agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption."

23. Despite Plaintiff's request for "meeting notes", "emails", "phone calls" and "discussions" with other federal agencies and automotive companies, the FDA provided none of these records. In the FOIA response, the FDA did not provide the name or qualifications of the

secret organization that reviewed the Soft Lights Foundation petitions, none of the meeting notes, none of the emails and none of the discussions which form the administrative record.

24. In the FOIA Response, the FDA did not provide the 2016 TEPRSSC Transcript which contains some of the "meeting notes" that Plaintiff had requested.

25. In its FOIA response, the FDA did not provide any communications between the FDA and NHTSA which would show the decision-making process as to how the FDA and NHTSA decided not to establish and maintain a liaison to test and evaluate LED headlamps.

26. Thus, despite Plaintiff's attempts to access the administrative record, the FDA once again acted dishonestly and in bad faith and did not provide the requested information.

VI. DOCUMENTS WITHELD

27. The Administrative Record consists of documents and dates showing that the government engaged in reasoned decision making. In an APA action, the Court must review those documents to make its determination as to whether the government acted properly. The government withheld the following documents and dates from the Court in acts of bad faith.

28. A) TEPRSSC Charter.

29. B) 2016 TEPRSSC Meeting Transcript.

30. C) Date of decision to not fill the 11 vacancies on TEPRSSC.

31. D) Date of decision to not hold a TEPRSSC meeting under the 2022 TEPRSSC Charter.

32. E) Justification for bypassing TERPRSSC and using a Secret Organization to review Soft Lights Foundation petitions to regulate LED products.

33. F) Change.org citizen petition comments showing that LED headlamps are dangerous and defective.

34. G) Documents showing FDA planning, conducting, coordinating, and supporting research, development, training, and operational activities to minimize the emissions of and the exposure of people to unnecessary light from LED headlamps.

35. H) Documents showing FDA and NHTSA techniques, equipment, and programs for testing LED headlamps for health impacts, as required by 21 U.S.C. 360ii(a)(6)(A).

36. I) Meeting date between NHTSA and FDA where determination was made not to establish and maintain a liaison for LED headlamps.

37. J) Justification to not to establish and maintain a liaison between NHTSA and the FDA for LED headlamps as required by 21 U.S.C. 360ii(a)(6) and given the tens of thousands of reports of harm from exposure to LED headlamps.

VI. CONCLUSION

38. While there are many more examples of bad faith actions by the government in this case, the examples above provide more than enough evidence for Plaintiff's strong showing of bad faith actions by the government.

39. Based on the acts of bad faith by the government, Plaintiff respectfully requests that this Court direct Mr. Kennedy and Defendant to comply with Rule 26(f) and automatically provide all discovery information for this case.

Dated: December 26, 2024

Respectfully Submitted,

By: /s/ Mark Baker
9450 SW Gemini Drive PMB 44671
Beaverton, OR 97008
mbaker@softlights.org

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.

U.S. FOOD & DRUG ADMINISTRATION

December 16, 2022

In Reply refer to
FOIA Control #:
2022-8833

Requester reference:

SOFT LIGHTS FOUNDATION
MARK BAKER
9450 SW Gemini Drive
PMB 44671
Beaverton OR 97008 US

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

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.

In processing your FOIA request, FDA will apply, as appropriate, the FOIA exemptions in 5 USC 552(b) and the foreseeable harm standard in 5 USC 552(a)(8)(i). We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm.

Due 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. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

If you have any questions about your request, please call Sarah B. Kotler, Director, Division Of Freedom Of Information, at (301) 796-8976 or write to us at:
Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the FOIA control number provided above which will help us to answer your questions more quickly.

You also have the right to seek dispute resolution services from:

Office of Government Information Services
National Archives and Administration
8601 Adelphi Road – OGIS
College Park, MD 20740-6001
Telephone:202-741-5770
Toll-Free: 1-877-684-6448
Email:ogis@nara.gov
Fax: 202-741-5769

and/or

FDA FOIA Public Liaison
Office of the Executive Secretariat
US Food and Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
Email: FDAFOIA@fda.hhs.gov

Sincerely,

SARAH KOTLER
Director

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

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

U.S. FOOD & DRUG ADMINISTRATION

September 26, 2024
FOIA request #: 2022-6020

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

Dear Mark Baker:

This letter is in response to your Freedom of Information Act (FOIA) request dated August 17, 2022, and received by the Food and Drug Administration (FDA) on August 17, 2022. Your request asked for 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.

In order to determine material responsive to your request, coordination with CDRH's Office of Policy was conducted. During this coordination, 19 pages of records responsive to your request were located. These records are being released to you in full. This completes the response from the FDA.

If you are not satisfied with any aspect of the processing and handling of this request, please contact MIchael Jenack, who processed this request by email at michael.jenack@fda.hhs.gov. 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.

X The following charges may be included in a monthly invoice:

Reproduction: $0.00 Search: $0.00 Review: $0.00 Other: Total: $ 0.00

The above total may not reflect final charges for this request. Please **DO NOT** send payment unless you secure an invoice for the total monthly fee.

Sincerely,

Leif M. Collins

Digitally signed by Leif M. Collins
Date: 2024.09.26 17:47:04 -04'00'

Leif M. Collins
Assistant Director, FOI Disclosure Team A
Division of Information Disclosure
Office of Communication and Content Development
Office of Communication, Information Disclosure, Training and Education (OCITE)
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Gmail

Mark Baker <mbaker@softlights.org>

FDA Freedom of Information Request - Case# 2022-6020

Jenack, Michael <Michael.Jenack@fda.hhs.gov> Fri, Sep 27, 2024 at 10:51 AM
To: "mbaker@softlights.org" <mbaker@softlights.org>

Dear Mark Baker,

The attached is our response to your FOIA request to the FDA dated August 17, 2022.

V/r

Mike

Michael Jenack

Government Information Specialist

Freedom of Information Disclosure Team A2

Division of Information Disclosure (DID)

Office of Communication and Content Development (OCCD)

Office of Communication, Information Disclosure, Training and Education (OCITE)

Center for Devices and Radiological Health (CDRH)

U.S. Food and Drug Administration (FDA

Michael.Jenack@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

Excellent customer service is important to us.

Please take a moment to provide feedback regarding the customer service you have received:

https://www.research.net/s/cdrhcustomerservice?ID=3132&S=E

2 attachments

CDRH_FOIA_Responsive Records_2022-6020_Full Release.pdf
8029K

Final Response Letter_2022-6020_signed.pdf
184K

Gmail

Mark Baker <mbaker@softlights.org>

FDA Freedom of Information Request - Case# 2022-6020

Mark Baker <mbaker@softlights.org> Fri, Sep 27, 2024 at 11:35 AM
To: Michael.Jenack@fda.hhs.gov
Cc: michelle.tarver@fda.hhs.gov, CDRH Ombudsman <CDRHOmbudsman@fda.hhs.gov>, "Kennedy, Scott P." <Scott.P.Kennedy@usdoj.gov>, "Kaufman, Patricia" <Patricia.Kaufman@fda.hhs.gov>

Dear Michael Jenack,

I am in receipt of your email regarding my FOIA request from December, 2022, in which you claim that there exists only a single document related to LED lights and that this document is the denial letter that the FDA sent to the Soft Lights Foundation on May 24, 2024. The FDA did not provide the following information:

1. Any and all documents involving ECRI and their investigation that led to the May 24, 2024 denial letter from the FDA.
2. Any and all communications between ECRI and the FDA regarding LED lights.
3. Any all all communications between the FDA and NHTSA, EPA, Access Board, FAA, OSHA, CPSC, DOE, DOT, FHWA, and all other federal agencies regarding LED products such as LED vehicle headlights, LED streetlights, LED General Service Lights, LED flashing lights, LED appliance indicator lights, LED lights on aircraft, and all other LED products.
4. Any and all discussions and meeting notes from TEPRSSC related to LED products.
5. Any and all discussions as to how and why TEPRSSC was dissolved.
6. Any and all internal FDA emails and meeting notes which discuss any aspect of an electronic radiation control program for LED products.

As noted in my appeal to the FDA, I wrote "My FOIA request is that the FDA provide all records related to this situation." and "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."

In its response letter regarding my FOIA request, the FDA provided only the single 19-page denial letter. The FDA made no claim that any of the above-referenced information is privileged, and in fact, the FDA has sent me letters stating, "While FDA does not provide information on ongoing investigations, information can be obtained pursuant to a Freedom of Information Act (FOIA) request, once an investigation is closed." Therefore, all documents involving ECRI (the third-party that investigated LED products), should have been disclosed to me, as well as all internal FDA communications involving LED products and the electronic radiation control program.

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.

Sincerely,

Mark Baker
President
Soft Lights Foundation
www.softlights.org
mbaker@softlights.org
[Quoted text hidden]

2 attachments

CDRH_FOIA_Responsive Records_2022-6020_Full Release.pdf
8029K

Final Response Letter_2022-6020_signed.pdf
184K

Gmail

Mark Baker <mbaker@softlights.org>

FDA Freedom of Information Request - Case# 2022-6020

Mark Baker <mbaker@softlights.org> Thu, Oct 3, 2024 at 7:39 AM
To: Michael.Jenack@fda.hhs.gov
Cc: michelle.tarver@fda.hhs.gov, CDRH Ombudsman <CDRHOmbudsman@fda.hhs.gov>, "Kennedy, Scott P." <Scott.P.Kennedy@usdoj.gov>, "Kaufman, Patricia" <Patricia.Kaufman@fda.hhs.gov>, "Knieser, Brian" <Brian.Knieser@mail.house.gov>, "Durand, Adam" <Adam.Durand@mail.house.gov>

Mr. Jenack,

You did not respond to my request from September 27, 2024. Attached is an acknowledgement letter that I received from the FDA Division of Radiological Health regarding LED radiation exposure reports. I have received several of these letters over the past 2+ years. The letter states, "While FDA does not provide information on ongoing investigations, information can be obtained pursuant to a Freedom of Information Act (FOIA) request, once an investigation is closed. Requests for information may be online at the following address: http://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm" Despite my FOIA request from 2022, and despite this letter from the FDA, and despite the FDA closing the investigation into LED radiation, you did not provide any information about the investigation other than the 19-page denial letter. You didn't provide any of the communications, research, TEPRSSC analysis, or any other information involving the FDA's radiation control program for LED products.

Due to FDA's willful, conscious, and illegal acts, it is my intent to sue the FDA for violation of the Freedom of Information Act.

Sincerely,

Mark Baker
President
Soft Lights Foundation
www.softlights.org
mbaker@softlights.org
[Quoted text hidden]

COR24000259-000.pdf
21K

U.S. FOOD & DRUG ADMINISTRATION

May 24, 2024

Mark Baker, President
Soft Lights Foundation
9450 SW Gemini Drive PMB 44671
Beaverton, OR 97008

Sent via email to: mbaker@softlights.org

Re: Citizen Petition – Docket Numbers FDA-2022-P-1151, FDA-2023-P-0233, FDA-2023-P-3828, and FDA-2023-P-3879

Dear Mr. Baker:

This Response is to the above referenced citizen petitions dated and filed with the Food and Drug Administration (FDA or Agency) on June 13, 2022, January 22, 2023, September 6, 2023, and September 10, 2023, respectively. In addition to the petitions, you submitted numerous supplements to the petitions, and there were also numerous public comments. For example, for citizen petition FDA-2022-P-1151, there were about 195 public submissions through January 31, 2024, with about 120 of those supplements to your petition submitted by you. Because your petitions generally raise similar scientific and technical concerns related to electromagnetic radiation emitted by products that use light emitting diodes (LEDs) and make similar requests to establish new regulations to restrict such radiation, for efficiency we are addressing all four petitions in this Response.

Having considered the petitions and the public comments included in the public dockets established for the petitions, under 21 CFR 10.30(e)(3), for the reasons described below, FDA is denying your requests.

I. Actions Requested

- In citizen petition FDA-2022-P-1151 ("CP1") you request that FDA "issue 21 CFR Part 1040.40 to regulate electromagnetic radiation in the visible portion of the spectrum emitted by products that use light emitting diodes (LEDs) and that these regulations set restrictions on spatial non-uniformity, chip-level peak luminance and peak radiance, spectral power distribution, and square wave flicker to protect the physical and psychological health, safety, comfort, and civil rights of those who are negatively impacted by LED light."

  You also request that FDA issue a finding that makes it clear to the industry that LEDs cannot be claimed to be energy efficient.

- In citizen petition FDA-2023-P-0233 ("CP2") you request that FDA "issue 21 CFR Part 1040.41 to regulate electromagnetic radiation in the visible portion of the spectrum emitted by products that use [LEDs] that pulse, flash, or strobe, and that these regulations set restrictions on spatial non-uniformity, chip-level peak luminance and peak radiance, spectral power distribution, synchronous and asynchronous flash rates, and rise and decay characteristics, and that the regulations be designed to protect the physical and psychological health, safety, comfort, and civil rights of those who are negatively impacted by LED strobe lights."

  In addition, CP2 requests that FDA formulate these rules to eliminate the discriminatory barriers created by LED strobe and flashing lights.

- In citizen petition FDA-2023-P-3828 ("CP3") you request that FDA "issue 21 CFR Part 1040.50 – LED Vehicle Lights to regulate electromagnetic radiation in the visible portion of the spectrum emitted by products [with] [LEDs] that are used on vehicles,[1] and that these regulations set restrictions on spatial non-uniformity, chip-level peak luminance and peak radiance, dispersion characteristics, spectral power distribution, digital flicker, pulse width modulation, synchronous and asynchronous flash rates, and rise and decay characteristics, and that the regulations be designed to protect the physical health, neurological health, psychological health, safety, comfort, cognitive functioning, vision, and civil rights of all individuals, especially those who are negatively impacted by LED radiation."

  In addition, CP3 requests that FDA publish 21 C.F.R. 1040.50 containing performance standards for LED vehicle lights which ensure the protection of all individuals, including those who are most sensitive to LED radiation such as individuals with epilepsy, migraines, autism, PTSD and other photosensitive individuals, and which prohibits the use of LED lighting on vehicles when the comfort, health, safety, or civil rights of all individuals cannot be ensured.

- In citizen petition FDA-2023-P-3879 ("CP4") you request that FDA "issue 21 CFR Part 1040.60 – LED Street Lights to regulate electromagnetic radiation in the visible portion of the spectrum emitted by products that use [LEDs] for street lighting,[2] and that these regulations set restrictions on spatial non-uniformity, chip-level peak luminance and peak radiance, dispersion characteristics, spectral power distribution, digital flicker, pulse width modulation, and that the regulations be designed to protect the physiological health, physical health, neurological health, psychological health, circadian rhythms, safety, comfort, cognitive functioning, vision, and civil rights of all individuals, especially those who are negatively impacted by LED radiation."

  In addition, CP4 requests that FDA formulate these rules to eliminate the discriminatory

[1] CP3 defines LEDs that are used on vehicles to include "headlamps, taillights, brake lights, turn signals, flashing lights, Daytime Running Lights, backup lights, and all other external light sources on vehicles." CP3 at 3.
[2] CP4 defines LED street lighting to include "bollard style and pole style light fixtures used to illuminate streets, roads, highways, freeways, sidewalks, and bicycle paths." CP4 at 3.

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10903 New Hampshire Avenue
Silver Spring, MD 20903
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barriers created by LED street lights.

For purposes of this response, we have interpreted your requests as asking FDA to conduct rulemaking to establish performance standards for LEDs emitting wavelengths in the visible portion of the spectrum that are used in products that are not medical devices, as that term is defined in section 201(h)(1) of the FD&C Act.[3] Therefore, we have not addressed LED lights intended to be used as, or as a part of, medical devices. Further, consistent with sections 532(a) and 1003(b)(2)(E) of the FD&C Act, this response focuses on impacts to human health and safety from electronic product radiation raised in your petitions, and not other impacts from electronic product radiation raised in your petitions, such as annoyance or distraction due to LEDs (CP2 at 16).

II. Legal Background

FDA is responsible for regulating radiation-emitting electronic products through the Electronic Product Radiation Control provisions of the FD&C Act (originally enacted as the Radiation Control for Health and Safety Act of 1968), which are in sections 531 through 542 of the FD&C Act ("Radiation Control provisions"). The Radiation Control provisions apply to any "electronic product," which is defined as: "(A) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or (B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation." (FD&C Act section 531; see also 21 CFR 1000.3(j)).

Under the Radiation Control provisions, FDA has established and carries out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation (see section 532 of the FD&C Act). Pursuant to the program, FDA regulates by developing and administering performance standards the manufacturers of radiation emitting electronic products, including both electromagnetic (ionizing and non-ionizing) and sonic radiation.[4] These products include those that emit visible light,[5] which

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[3] Section 201(h)(1) of the FD&C Act defines a device as: "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is –
(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplements to them,
(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
(C) intended to affect the structure or any function of the body of man or other animals, and
which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

[4] Section 531 of the FD&C Act ("(1) the term 'electronic product radiation' means - (A) any ionizing or non-ionizing electromagnetic or particulate radiation, or (B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product"); see also 21 CFR 1000.3(i) and (k).

[5] 21 CFR 1000.15.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
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includes LEDs. As part of the program, FDA, among other things, must conduct certain activities related to electronic products to "minimize the emissions of and the exposure of people to, unnecessary electronic product radiation." These activities include "plan[ning], conduct[ing], coordinat[ing], and support[ing] research, development, training, and [other] operational activities" (section 532(a)(2) of the FD&C Act).

Separately, if FDA determines that emissions of and exposure to unnecessary electronic product radiation need to be controlled for the protection of the public health and safety, sections 534 and 535 of the FD&C Act describe the Agency's responsibilities relating to the: (1) development of performance standards; and (2) notification to manufacturers of failures to comply or product defects, as applicable:

- Section 534(a)(1) of the FD&C Act states that "The Secretary[6] shall by regulation prescribe performance standards for electronic products to control the emission of electronic product radiation from such products *if* he determines that such standards are necessary for the protection of the public health and safety." (Emphasis added).
- Section 535(e) of the FD&C Act states that "*[i]f*… the Secretary determines that any electronic product … (1) does not comply with an applicable standard …; or (2) contains a defect,"[7] then "he shall immediately notify the manufacturer of such product of such defect or failure to comply." (Emphasis added).

As part of the electronic product radiation control program, section 532(a)(1) incorporates activities conducted pursuant to section 534.

Currently, FDA has no established performance standards for LED lights, though manufacturers of LED lights are responsible for compliance with all applicable requirements of Title 21 Code of Federal Regulations (Subchapter J, Radiological Health) Parts 1000 through 1005.

III. Brief Overview of the Citizen Petitions

The petitions assert that Congress, through the Radiation Control for Health and Safety Act of 1968 (i.e., the Radiation Control provisions) has "mandated" that FDA regulate electromagnetic radiation from electronic products, including visible light, and indicate that FDA is required under the Radiation Control provisions to issue a rule to regulate electromagnetic radiation in the visible portion of the spectrum emitted by products that use LEDs or specific

[6] "Secretary" as used in the quoted statutes refers to the Secretary of the Department of Health and Human Services, who has delegated these determinations to the FDA. See SMG1410.10 available at: https://www.fda.gov/media/81983/download.

[7] See 21 CFR 1003.2 for the definition of "defect." A product such as an LED that utilizes electronic product radiation to accomplish its primary purpose and from which such emissions are intended has a defect which relates to the safety of use by reason of the emission of electronic product radiation if it: (1) Fails to conform to its design specifications relating to the emission of electronic product radiation; or (2) Without regard to the design specifications of the product, emits electronic product radiation unnecessary to the accomplishment of its primary purpose which creates a risk of injury, including genetic injury to any person; or (3) Fails to accomplish the intended purpose. 21 CFR 1003.2(b).

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

type of LEDs (e.g., CP1 at page 2). The petitions assert that the Radiation Control provisions, and more specifically sections 532(a), 532(a)(2), and 534 of the FD&C Act, require FDA to minimize emissions of radiation from LED products, minimize the public's exposure to LED radiation, and, that unless evidence shows that the LED lights that are the subject of the petitions are safe for everyone, prohibit the use of LEDs (CP3 at 13, CP4 at 12). CP3 and CP4 state that section 532(a)(6)(B) of the FD&C Act directs the FDA to consult and maintain liaison with other federal agencies in the development of performance standards pursuant to section 534 and determine if it is even possible to make LED vehicle lights and street lights that do not trigger negative health effects (CP3 at 13; CP4 at 12). Each petition asserts that federal agencies rely on FDA to develop performance standards for radiation emissions from LEDs, and that as a result FDA now becomes responsible for setting standards for federal agencies that regulate traditional light sources (see, e.g., CP3 at 11; CP4 at 10). Further, CP4 asserts that pursuant to 21 CFR 1003.2(b) LED streetlights are a defective product because they "emit a visible radiation type that is unregulated, is a recognized hazard, and which does not provide safe, uniform illumination" (CP4 at 13).

The petitions assert that LED light is qualitatively different from other types of light sources and describe various characteristics of LED light sources for which you request regulation by FDA (e.g., spatial non-uniformity, chip-level peak luminance and peak radiance, dispersion characteristics, spectral power distribution, digital flicker, pulse width modulation, etc.). The petitions assert that as a result of these characteristics of LED light, the electronic product radiation from products that use LEDs cause negative health effects.[8] The petitions also assert that LED lights have a negative impact on the environment and non-human biological systems.

In support of the petition requests, you provide or reference various types of information including but not limited to: photos, videos, illustrations, personal stories/testimony, scientific articles, research studies, news stories, state administrative proceeding documents, consensus standards, webpages, industry blogs, advertisements, white papers, opinion articles, a description of a warning label on a commercial flashlight, correspondence with federal and state agencies, and comments in a grassroots petition to ban LED headlights. As described further below, FDA considered these references, as appropriate, in drafting this Response.

IV. Requests Outside the Scope of FDA Authority

To the extent that your requests seek a declaration regarding the energy efficiency of LED lights, a remedy under the Americans with Disabilities Act and/or protection against a

[8] For instance, CP1 asserts that "[t]he low quality of LED light has been shown to have significant negative impacts on human health, safety, and comfort, including causing epileptic seizures, migraines, panic attacks, nausea, loss of balance, reduced visual perception, anxiety, anger, agitation, and eye injury" (CP1 at 6); CP2 asserts that "LED strobing and flashing lights have been documented to cause life-threatening photosensitive seizures, multi-day migraines, and anxiety panic attacks. The intensity of LED strobe lights may be causing permanent eye damage" (CP2 at 2-3); CP3 asserts that, among other things, "LED vehicle lights have been shown to cause serious harm and injury, including nausea, panic attacks, seizures, reduced cognitive functioning, impaired vision, eye pain, and eye injury" (CP3 at 18); and CP4 asserts that, among other things, LED street lights have been shown to cause "nausea, panic attacks, seizures, reduced cognitive functioning, impaired vision, eye pain, and eye injury" (CP4 at 18).

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

direct violation of an individual's "right to visual freedom" (see, e.g., CP2 at 14), or a determination based upon impacts to non-human biological systems, these requests are outside the scope of the citizen petition process outlined in 21 CFR 10.30, as they request relief that is not available under the laws administered by the FDA. Pursuant to the Radiation Control provisions, FDA is tasked with protecting the public health and safety from exposure to unnecessary radiation from electronic products.[9] Assessing energy efficiency and protecting non-human biological systems from electronic product radiation are not within the scope of FDA's authorities. Further, while the petitions request FDA to issue regulations to protect, among other things, "civil rights of those who are negatively impacted by LED light," (see, e.g. CP1 at 1) and state that LED lights "violate citizen's [sic] right to visual freedom" (see e.g., CP3 at 18) and that LED lights are discriminatory (see e.g., CP2 at 13), FDA is not directly responsible for enforcing anti-discrimination and civil rights laws.

V. Discussion

a. FDA Is Not Required to Prescribe Performance Standards to Control Electronic Product Radiation Emitted by LEDs

The scope of FDA's authority under the Radiation Control provisions to protect the public health and safety from electronic product radiation is extensive, as any product with an electronic circuit will emit some radiofrequency radiation. However, many do not pose unnecessary emission and exposure risks. Organizational units within FDA's Center for Devices and Radiological Health (CDRH) and Office of Regulatory Affairs (ORA) undertake relevant research, development, training, and operational activities. FDA seeks to make optimal use of its authorities and resources to benefit public health and safety. FDA engages with stakeholders and undertakes research to identify the types of products where there is clear and strong evidence of a risk to human health. For those product types, FDA undertakes activities to control the emissions of and the exposure of people to unnecessary electronic product radiation.

We disagree that Congress "mandated and directed the Food and Drug Administration to publish regulations and restrictions for electromagnetic radiation emitted by electronic products" (CP2 at 3) without qualification or for LEDs specifically. As noted above, sections 532(a)(1) and 534(a) require FDA to develop and administer performance standards for electronic products *if* the Agency determines that such standards are necessary for the protection of the public health and safety. While FDA agrees that section 532(a)(6)(B) of the FD&C Act directs FDA to consult and maintain liaison with other appropriate federal departments and agencies on the development of performance standards to control electronic product radiation, FDA's initial decision whether to engage in the development of a performance standard is based upon the determination under section 534(a) of the FD&C Act.

FDA generally does not consider issuing regulations for specific performance standards for every type of electronic product to be necessary given the effectiveness of existing mitigations in addressing unnecessary radiation and alternative approaches to protect public

[9] See section 532 of the FD&C Act.

U.S. Food & Drug Administration
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Silver Spring, MD 20903
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health (e.g., manufacturers' voluntary compliance with consensus standards, applicability of other types of controls, FDA's ability to leverage stakeholder collaborations) as well as the fact that most products do not produce types or levels of unnecessary radiation that pose a risk to public health. For LEDs, due to their long history of safety with respect to the visible wavelengths being emitted, historically FDA has not considered performance standards to control the radiation from LEDs in the visible wavelengths to be necessary for the protection of the public health and safety.

We also disagree with your assertion that when taken together the statutes make clear that Congress directs the FDA to minimize emissions of radiation from LED products and minimize exposure of the public to radiation from LED products (CP3 at 12; CP4 at 11). As explained in Section II, minimizing emissions and exposure of people to *unnecessary* radiation from radiation emitting electronic products is referenced in the Radiation Control provisions at section 532(a)(2) of the FD&C Act in the context of planning, conducting, coordinating, and supporting research, development, training, and other operational activities. In terms of performance standards, section 534 of the FD&C Act does not state or imply that FDA must issue them to minimize exposure to radiation from electronic products, either generally or from LEDs specifically.

b. Petitioner Provided Insufficient Evidence that the Requested Performance Standards Are Necessary for the Protection of Public Health and Safety

As described in Section III of this Response, in support of the petition requests, you provided FDA with various types of information. FDA also received information in the form of comments to the petition docket. FDA has considered, as appropriate, the information you provided with the petitions and comments submitted to the petition dockets on or before January 31, 2024.[10] When making regulatory decisions, FDA generally gives scientific data and expert opinions (together, "scientific information") much greater weight than personal stories or experiences because the latter report on the experience of a single individual and are difficult to generalize. For instance, individual reports generally do not provide all factors that may be contributing to any adverse health effects, the extent of the population that may be impacted, under what conditions, and the characteristics of products, if any, that pose a risk. Similarly, while photos and videos of LED lights, voluntary warning labels on electronic products, product advertisements, and news stories without scientific content or references may be illustrative and also provide some context, they do not provide any scientific evidence on which to base a determination regarding the impact of the electronic product radiation emitted from such products on public health. FDA seeks scientific consensus from multiple independent and well-conducted research studies to understand the underlying cause, risks, mitigation, and other factors to confidently develop standards. Accordingly, while we considered them, our discussion below of each petition does not address personal stories and experiences, including those in the

[10] Due to the high volume of petition supplements and public comments that FDA received on an ongoing basis, FDA needed a cut-off date to consider them and draft the response. Among the information to be included in a citizen petition is a full statement of the factual and legal grounds on which the petitioner relies, including all relevant information and views on which the petitioner relies, as well as representative information known to the petitioner which is unfavorable to the petitioner's position (21 CFR 10.30(b)(3)).

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
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form of news stories, photos, and videos, and warnings on commercial products or in product advertisements. Instead, the focus of this Response is on the scientific data provided to FDA through the petition process. Moreover, we generally did not focus on petitions or correspondence between the Petitioner and other federal, state, and local agencies, state administrative proceedings, and complaints to state public health and other regulatory authorities when the reasons for submitting them were unclear or the information appeared to be duplicative of information submitted with these petitions.

For each petition, FDA has determined that you have not shown that the regulations you request to control the emission of electronic product radiation from the LED products described is necessary for the protection of the public health and safety. For CP4, we have determined that the information you provided to the Agency is insufficient to demonstrate that the LED used in any particular streetlight has a defect pursuant to 21 CFR 1003.2(b), i.e., emits electronic product radiation unnecessary to the accomplishment of its primary purpose which creates a risk of injury, including genetic injury, to any person. During our consideration, where more than one petition requests a restriction on the same characteristic of LED light, we considered the entirety of pertinent information provided in support of that restriction.

1. Response to CP1

CP1 requests that FDA issue a regulation to regulate electromagnetic radiation in the visible portion of the spectrum emitted by products that use LEDs and that these regulations set restrictions on specific characteristics of LED light, specifically: spatial non-uniformity, chip-level peak luminance and peak radiance, spectral power distribution, and square wave flicker[11] to protect those who are negatively impacted by LED light. CP2, CP3, and CP4 also request restrictions on these characteristics for the LED light types that are the subject of those petitions. Our analysis of the scientific information, including technical illustrations, scientific research and technical articles, consensus standards, and publications by standards organizations, you provided to support your requested restrictions is set forth below. As explained, FDA has determined that the information provided in support of CP1 is insufficient to demonstrate a regulation to control electromagnetic radiation in the visible portion of the spectrum emitted by products that use LEDs is necessary to protect the public health and safety at this time.

- Spatial Non-uniformity: CP1 and the other three petitions request that FDA restrict spatial non-uniformity of LED lights. CP1 asserts that LED light is a low-quality light, in part because of its spatial non-uniformity (CP1 at 3), which has impacts on human nerves (CP1 at 8). CP3 and CP4 assert that spatially non-uniform light is unsafe because it is more difficult for the nerves and brain to process (CP3 at 15; CP4 at 14). However, you provided no scientific information supporting the asserted adverse health impacts from LED spatial non-uniformity. For instance, in CP1 you provided an article that discusses calculation of the intensity distribution for flat LED light sources, but the article does not

[11] The terms "spatial non-uniformity", "luminance", "radiance", "spectral power distribution", and "flicker", as understood and used by FDA, are defined in the IEC glossary ("IEC Glossary") available at: https://products.iec.ch/view/search/all?q=eyJtb2RlIjoiR0xPU1NBUlkiLCJzb3J0QnkiOiJ0ZXJtLS1hc2MiLCJsYW5ndWFnZSI6ImVuIn0%3D

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

discuss any public health issue associated with spatial non-uniformity of LEDs.[12] Moreover, you acknowledge in CP1 the "lack of formal, supervised study of the impacts of the spatially non-uniform energy of LED light on humans" (CP1 at 7). The only information you provided was personal stories attributing adverse reactions to the spatial non-uniformity of LED lights, which does not sufficiently support a connection between spatial non-uniformity of LEDs and public health issues.

You assert that "LED light has different energies and characteristics at every point in 3D space and that previous formulas, calculations, and regulations that assumed uniform luminance cannot be used with LED light" (CP1 at 5-6). FDA understands that LED light has different energies and characteristics at every point in 3D space and agrees that this should be taken into account when appropriate. This is consistent with internationally accepted consensus standards, such as IEC 62471:2006[13] published by the International Electrotechnical Commission (IEC) and ANSI/IESNA RP-27[14] published by the American National Standards Institute (ANSI) and the Illuminating Engineering Society of North America (IESNA), which provide guidelines for lamps with spatially uniform and spatially non-uniform optical outputs, and recommend measurement at different points for spatially non-uniform light.

FDA finds the evidence you provided insufficient to demonstrate a need to restrict non-spatial uniformity of LED lights to protect public health and safety from unnecessary electronic product radiation.

- Spectral Power Distribution: CP1 and each of the other petitions request that FDA set a restriction on spectral power distribution of LED lights and express concerns about the asserted negative effects of LED light's spectral power distribution, particularly the impact of blue wavelength light, on human health. Alleged risks include acute and long-term eye damage (see, e.g., CP1 at 6-7, 9, CP3 at 15, CP4 at 14) and sleep-wake/circadian rhythm interference (CP1 at 24; CP4 at 14-15, 16), including an increased risk of various health conditions (e.g., prostate cancer, breast cancer, thyroid cancer, mood disorders, diabetes, heart disease, obesity, premature birth, and early mortality) due to such interference (CP4 at 14-15). You also assert that LEDs' blue wavelength causes dangerous glare (CP1 at 15; CP3 at 15, CP4 at 14).

  FDA is aware of research on blue light's impact on circadian rhythm,[15] but currently finds a regulation prescribing a performance standard on LED color temperature is not

[12] Khan, MN. "Derivation and Experimental Verification of the Near-field 2D and 3D Optical Intensities From a Finite-size Light Emitting Diode (LED)," in *IEEE Photonics Journal*, 11.6 (2019): 1-19, Art no. 8201219, doi: 10.1109/JPHOT.2019.2948816.
[13] IEC 62471:2006, "Photobiological safety of lamps and lamp systems."
[14] ANSI/IES RP-27-20, "Recommended Practice: Photobiological Safety For Lighting Systems."
[15] See materials from the October 25-26, 2016, meeting of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) available at https://www.fda.gov/advisory-committees/technical-electronic-product-radiation-safety-standards-committee/2016-meeting-materials-technical-electronic-product-radiation-safety-standards-committee.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
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necessary to protect public health and safety. The research articles provided to support the effect of blue wavelength light, including LEDs, on sleep-wake/circadian rhythms[16] are consistent with our current knowledge and do not change this determination. If there are concerns with disruption of sleep patterns and circadian rhythm due to blue light exposure, alternative approaches, such as efforts to raise awareness of color temperature lighting options or other means of controlling exposure to blue light from LEDs, may, for instance, be an appropriate approach.[17] The research articles referenced (e.g., in CP4 and comments to the docket) about secondary health effects resulting from circadian rhythm disruption do not establish a causal link between exposure to LED blue light and the health complications listed in CP4 and have significant limitations.[18] For instance, some of the referenced articles use satellite data to estimate exposure to artificial light at night.[19] Satellite data does not demonstrate how much light/blue light gets into a person's house and how much a person is exposed to blue light. A number of the studies used wrist light detectors that do not provide an estimate of light/blue light at the ocular level.[20] A majority of the referenced studies rely on cross-sectional designs, which inherently pose limitations in establishing causation due to their static nature, i.e., they provide information at a specific point in time only.[21] A recently published statement by the International Commission on Non-Ionizing Radiation Protection (ICNIRP) on the effects of artificial lighting on circadian rhythm disruption supports our findings. The article discusses both primary effects (i.e., sleep-awake/circadian rhythms) and long-term secondary effects (e.g., cancer, etc.) of blue light and concludes that due to limited data

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[16] See, e.g., Sánchez de Miguel, A., Bennie, J., Rosenfeld, E., et al. "Environmental risks from artificial nighttime lighting widespread and increasing across Europe." *Science Advances* 8, eabl6891 (2022).doi:10.1126/sciadv.abl6891 ("Sanchez 2022"); Moore-Ede, M., Blask, D.E., Cain, S.W., et al. "Lights Should Support Circadian Rhythms: Evidence-Based Scientific Consensus." *Research Square*; (2023) PREPRINT (Version 1). doi: 10.21203/rs.3.rs-2481185/v1.

[17] We also note that some states and localities regulate light pollution and artificial lights at night. See, e.g., https://www.ncsl.org/environment-and-natural-resources/states-shut-out-light-pollution (last accessed May 23, 2024).

[18] See, e.g., Zhang, D., Jones, R.R., James, P., et al. "Associations between artificial light at night and risk for thyroid cancer: a large US cohort study." *Cancer* 127.9 (2021) ("Zhang 2021"): 1448-1458; Baugh, A., Buhr, R.G., Quibrera, P, et al. "Risk of COPD exacerbation is increased by poor sleep quality and modified by social adversity." *Sleep* 45.8 (2022): zsac107; Burns, A.C., Windred, D.P., Rutter, M.K., et al. "Day and night light exposure are associated with psychiatric disorders: an objective light study in> 85,000 people." *Nature Mental Health* (2023): 1-10 ("Burns 2023").

[19] See, e.g., Zhang 2021; Sanchez 2022; Lin, Li-Zi, et al. "Outdoor light at night, overweight, and obesity in school-aged children and adolescents." Environmental Pollution 305 (2022): 119306 ("Lin 2022"); Garcia-Saenz, A., de Miguel, A. S., Espinosa, A., et al. "Association between outdoor light-at-night exposure and colorectal cancer in Spain." *Epidemiology* 31.5 (2020): 718-727; Lu, Y., Yin, P., Wang, J., et al. "Light at night and cause-specific mortality risk in Mainland China: a nationwide observational study." *BMC medicine* 21.1 (2023): 1-11; Mazzoleni, E., Vinceti, M., Costanzini, S., et al. "Outdoor artificial light at night and risk of early-onset dementia: A case-control study in the Modena population, Northern Italy." *Heliyon* 9.7 (2023). Kim, S.H., Kim, Y.K., Shin, Y.I., et al. "Nighttime Outdoor Artificial Light and Risk of Age-Related Macular Degeneration." *JAMA Network Open* 7.1 (2024): e2351650-e2351650.

[20] Kim, M., Vu, T.H., Maas, M.B., et al. "Light at night in older age is associated with obesity, diabetes, and hypertension." *Sleep* 46.3 (2023): zsac130; Burns 2023.

[21] See, e.g., Burns 2023; Lin 2022.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

available (e.g., insufficient number of well-conducted epidemiological studies with regards to potential long-term adverse effects) and conflicting results, there is insufficient evidence to draw any conclusions.[22]

The studies you provided to support photochemical retinal injury from exposure to blue LED light[23] also have significant limitations. Each study used lengthy exposure conditions in an animal model (rodents; fruit flies; rabbits) and/or in vitro cells. The scientific determinism of such exposure limit experiments removes aversion responses to make the exposures repeatable and controlled. As a result, the hazards of real-life phototoxic exposures are overstated in these studies. Photochemical retinal hazard is present only for extended staring into painfully bright light sources, such as the sun, [24] and human aversion responses to bright lights naturally protect the retina from phototoxic exposures by pupillary contraction, blinking, squinting, and turning away. The Agency is currently aware of only two case studies of photochemical retinal injuries, both of which were caused by atypical exposure to blue-rich LED lights (i.e., staring directly into or repeated exposure to the light source).[25] Accordingly, FDA agrees with ICNIRP's 2020 Statement on LEDs ("ICNIRP 2020 Statement"), [26] "[in vitro and animal] studies [on blue and white LEDs] cannot be directly extrapolated to normal exposure conditions for humans, and equivalent effects can also be caused by the optical radiation from other light sources under extreme exposure conditions." We also agree with the ICNIRP's conclusion that "[i]njuries of this type appear to be very rare and unlikely to occur unless

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[22] Miller, S., Cajochen, C, Green, A., et al. "ICNIRP Statement on Short Wavelength Light Exposure from Indoor Artificial Sources and Human Health." *Health physics*, 126.4 (2024): 241–248. https://doi.org/10.1097/HP.0000000000001790.

[23] Shang, Y.M., Wang G.S., Sliney D., et al. "White light–emitting diodes (LEDs) at domestic lighting levels and retinal injury in a rat model." *Environmental health perspectives* 122.3 (2014): 269-276; Nash, T.R., Chow, E.S., Law, A.D, et al. "Daily blue-light exposure shortens lifespan and causes brain neurodegeneration in *Drosophila*." *npj Aging and Mechanisms of Disease* 5, 8 (2019); Ogawa K, et al. "Blueberry Stem Extract Suppresses Blue Light-Emitting Diode Light-Induced Endoplasmic Reticulum Stress on Retinal Photoreceptor Cells." *BPB Reports* 6.3 (2023): 87-97.; Chan, Y.J., Hsiao, G., Wan, W.N, et al. "Blue light exposure collapses the inner blood-retinal barrier by accelerating endothelial CLDN5 degradation through the disturbance of GNAZ and the activation of ADAM17." *Fluids and Barriers of the CNS* 20.1 (2023): 31.

[24] See e.g., Argilés, M., Sunyer-Grau, B., Arteche-Fernandez, S., et al. "Functional connectivity of brain networks with three monochromatic wavelengths: a pilot study using resting-state functional magnetic resonance imaging." *Scientific reports* 12.1 (2022): 16197. doi: 10.1038/s41598-022-20668-9; Tao, J. X., Zhou, W. C., & Zhu, X. G. "Mitochondria as potential targets and initiators of the blue light hazard to the retina." *Oxidative medicine and cellular longevity* (2019): 6435364. doi: 10.1155/2019/6435364; Li, X., Zhu, S., & Qi, F. "Blue light pollution causes retinal damage and degeneration by inducing ferroptosis." *Journal of Photochemistry and Photobiology B: Biology* 238 (2023):112617; Fireflier, "What is Photobiological safety standard?" (April 1, 2021) (last accessed January 8, 2024) available at: https://fireflier.com/what-is-photobiological-safety-standard/; Thomas, L. "Blue light and fruit flies: a warning for humans" News Medical Life Sciences website, October 18, 2019 (last accessed January 8, 2024) available at: https://www.news-medical.net/news/20191018/Blue-light-and-fruit-flies-a-warning-for-humans.aspx.

[25] Obana, A., Brinkmann, R., Gohto, Y., et al. "A case of retinal injury by a violet light-emitting diode" *Retinal Cases Brief Reports* 5:223–226; (2011); Zhang, L, et al. "Accidental macular injury from short-term exposure to a handheld high-intensity LED light." *Heliyon* 9.8 (2023) Jul 26;9(8):e18705. doi: 10.1016/j.heliyon.2023.e18705. PMID: 37554811; PMCID: PMC10404656,

[26] ICNIRP, "LIGHT-EMITTING DIODES (LEDS): IMPLICATIONS FOR SAFETY", HEALTH PHYS 118(5):549–561; 2020. [27] *Id.*

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the subjects purposely overcome their natural aversion response," and "[a]cute damage to the human retina from typical exposure to blue or white LEDs has not been demonstrated."[27] The petition states that infants are an identified high-risk population vulnerable to LED-exposure harm. FDA is aware of some research showing that infants' eyes might be more susceptible to blue-rich light.[28] However, we are aware of a very limited number of injuries reported in the scientific literature caused by overexposure to blue-rich LEDs, none of which involved young children or infants. Although there is insufficient information to warrant rulemaking at this time, precautionary care can be taken to protect the retina against close exposure of young children's or infants' eyes to high-intensity, blue-rich LEDs.

Other scientific and industry articles you provided to support a restriction on LEDs' spectral power distribution due to blue wavelength light either do not identify hazards to human health from blue wavelength LEDs or do not provide sufficient evidence of hazards to human health from blue wavelength LEDs under typical exposure conditions because the articles do not identify any hazards associated with blue light to human health.

In a comment supplementing CP1, you express concern for cumulative life-time exposure to LED blue light[29] and reference a chapter of a scientific handbook ("Martinsons Handbook") about photobiological safety of LEDs, and long-term effect of exposure to blue light.[30] This reference does not provide sufficient evidence of negative effects of cumulative life-time exposure to blue light. The Martinsons Handbook acknowledges that "[v]ery little is known about the effects of life-long cumulated exposures to blue light emitted by LEDs."[31] It also indicates that long-term effects are "estimated to be of negligible or small risk" by the IEC committee.[32] FDA also is aware of ICNIRP's references to studies about cumulative life-time exposure to blue light, and ICNIRP's statement that "[c]oncern for potential long-term effects, e.g., age-related macular degeneration (AMD), remains based on epidemiological studies indicating a link between high levels of exposure to sunlight and AMD."[33] According to ICNIRP, high levels of cumulative light exposure may lead to AMD.[34] However, this link is not proven.

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[27] *Id.*
[28] Point, S. "Blue light hazard: are exposure limit values protective enough for newborn infants." *Radioprotection* 53.3 (2018): 219-224.
[29] FDA-2022-P-1151-0048.
[30] Martinsons, Christophe. "Photobiological safety." Handbook of Advanced Lighting Technology, Cham, Switzerland, Springer International Publishing (2017): 865-895.
[31] *Id.* at 24.
[32] *Id.*
[33] ICNIRP 2020 Statement at 549.[34] *Id.* citing Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), "Opinion on Potential risks to human health of Light Emitting Diodes (LEDs)" (2018). [35] For vehicle headlights, FDA notes the National Highway Traffic Safety Administration (NHTSA) standard Federal Motor Vehicle Safety Standard (FMVSS) No. 108, Lamps, Reflective Devices, and Associated Equipment (49 CFR 571.108).
[34] *Id.* citing Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), "Opinion on Potential risks to human health of Light Emitting Diodes (LEDs)" (2018). [35] For vehicle headlights, FDA notes the National

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Moreover, the studies reviewed by ICNIRP involved exposure to sunlight, not LEDs or other types of artificial light, and the results were not consistent. As a result, they are not sufficient to demonstrate the existence of a public health and safety concern, and ICNIRP concludes that further research on potential health effects both from short- and long-term exposure is needed.

For glare, you provided personal stories but did not provide scientific evidence that glare due to LEDs impacts human health. To the extent you provided this information because of asserted concerns about glare on driving motor vehicles, this Response does not focus on those impacts for similar reasons as discussed in section I above.[35]

Based on the above discussion, FDA finds the evidence provided in support of the petitions insufficient to demonstrate a regulation restricting the spectral power distribution of LED lights in the visible range is necessary to protect public health and safety from electronic product radiation.

- Chip-Level Peak Luminance/Peak Radiance: CP1 and each of the other petitions request that FDA issue regulations for LED lights that set restrictions on chip-level peak luminance and peak radiance. In a comment supplementing CP1 you assert that when measuring the effects of 450nm blue wavelength light on eye cells or other molecular structures, luminance/radiance must be measured precisely at each point in space at the femtometer or picometer scale.[36] You assert that the luminance metric is typically used for dazzle, glare, discomfort, distraction, vision, perception, cognitive functioning, neurological impacts, and psychological impacts (CP3 at 14; CP4 at 13), and that using radiance and photobiological hazards "will not be sufficient to protect against glare, to ensure uniform roadway illumination, to address dispersion characteristics, or to ensure that LED headlights don't cause seizures or headaches."[37] As noted above, this Response does not focus on any impacts LEDs may have on driving motor vehicles, for example due to glare, and we do not address them here.

  In support of your request for restrictions on LED luminance, you cite a scientific review by the Epilepsy Foundation.[38] However, the Epilepsy Foundation review, which is discussed further below, does not set a limit on peak luminance but suggests a specific combination of luminance, flash rate, and visual field may create risk of photosensitive seizure for some individuals. You also state that human comfort is at 300 nits, and the

Highway Traffic Safety Administration (NHTSA) standard Federal Motor Vehicle Safety Standard (FMVSS) No. 108, Lamps, Reflective Devices, and Associated Equipment (49 CFR 571.108).

[35] For vehicle headlights, FDA notes the National Highway Traffic Safety Administration (NHTSA) standard Federal Motor Vehicle Safety Standard (FMVSS) No. 108, Lamps, Reflective Devices, and Associated Equipment (49 CFR 571.108).

[36] FDA-2022-P-1151-0050.

[37] FDA-2022-P-1151-0176. For definitions of luminance and radiance, see IEC Glossary available at https://products.iec.ch/view/search/all?q=eyJtb2RlIjoiR0xPU1NBUlkiLCJzb3J0QnkiOiJ0ZXJtLS1hc2MiLCJsYW5ndWFnZSI6ImVuIn0%3D. .

[38] Fisher, R.S., Acharya, J.N., Baumer, F.M., et al. "Visually Sensitive Seizures: An Updated Review by the Epilepsy Foundation." *Epilepsia*. 63.4 (2022): 739–768 ("Fisher 2022").

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maximum human tolerance is 50,000 nits.[39] To the extent human discomfort could be considered a risk to human health, you provide no valid evidence in support of this threshold. The industry document you cite in a comment supplementing CP1[40] to support the maximum visual tolerance of 50,000 nits does not indicate how these values were determined. The same reference also indicates that other conventional light sources (e.g., incandescent lamps), not just LEDs, exceed 50,000 nits, indicating that this is not an emerging health concern related to LEDs. While photometric measurements, such as luminance, could be appropriate for evaluating other effects like glare, you provided no scientific information that glare creates a risk of injury to human health.[41]

The petitions request that FDA set a restriction on chip-level peak radiance. You indicate that radiation from LEDs must be measured precisely at each point in space at the femtometer or picometer scale due to the small dimensions of an LED chip.[42] This assertion is in contradiction with IEC 62471, which warns against an overestimation of the hazard if the measured irradiance is averaged over a smaller aperture than specified in that standard's measurement technique: "The minimum size of the averaging aperture is related to physiological and behavioural factors that result in the averaging of the incident radiation over a certain surface area."[43] To the extent that you provided information intended to demonstrate effects of radiance on human health, such information is addressed elsewhere in this Response, e.g., in the discussions on spectral distribution and synchronous and asynchronous flash rates.

You raise concerns about radiation-induced thermal damage to the retina, but also acknowledge that the Martinsons Handbook states that "[t]he exposure levels needed to produce thermal damage on the retina cannot be met with light emitted by LEDs of current technologies."[44] You provide no other information regarding the potential for thermal damage to the retina caused by radiation emitted from LEDs in the visible spectrum. FDA agrees with the ICNIRP 2020 Statement "[b]ecause of their limited radiance (compared to lasers, for example), currently available LEDs are not likely to pose a retinal thermal hazard."[45]

FDA finds the evidence you provided insufficient to demonstrate a regulation restricting the chip-level peak luminance and peak radiance of LED lights is necessary to protect

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[39] See, e.g., FDA-2022-P-1151-0036.
[40] FDA-2022-P-1151-0050.
[41] Optical safety standards for LEDs or lamps, such as IEC 62471:2006, IEC 62471-7, and ANSI/IES RP-27-20, use radiometric units, not photometric units of luminance, luminous intensity or illuminance because the spectral luminous efficiency functions are not useful to the biophysics of retinal damage. See, e.g., Sliney DH. "International Commission on Illumination. Radiometric quantities and units used in photobiology and photochemistry: recommendations of the Commission Internationale de L'Eclairage (International Commission on Illumination)" *Photochemistry and Photobiology*. 2007 Mar-Apr;83(2):425-32. doi: 10.1562/2006-11-14-RA-1081. PMID: 17115802.[42] FDA-2022-P-1151-0050.
[42] FDA-2022-P-1151-0050.
[43] IEC 62471:2006, "Photobiological safety of lamps and lamp systems."
[44] See FDA-2022-P-1151-0050 at page 11 quoting Martinsons Handbook at 6.
[45] INCNIRP 2020 Statement at 556.

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public health and safety from electronic product radiation.

- Square Wave/Digital Flicker: CP1, CP3, and CP4 request that FDA establish regulations for LED lights that set restrictions on square wave/digital flicker, and CP3 and CP4 request restrictions on pulse width modulation, a form of temporal light modulation, when used to create deliberate flicker for dimming purposes. We treat these two characteristics as related because they are synonymous concepts and result in the same quality of the light source. You assert that flicker contributes to negative health effects including psychological hazards, vision impairment, headaches, annoyance, agitation, exhaustion, migraine, or seizure (see, e.g., CP4 at 15). Information you provided in support of this request included: a professional society newsletter, white papers, a scientific literature review, an IEEE standard, personal stories, correspondence, and articles.

  Some evidence suggests some individuals associate health effects, like migraines, with temporal light modulation. For instance, ICNIRP's 2020 Statement indicates that a proportion of the population may experience symptoms such as headaches and migraine from LED, whether or not associated with temporal light modulation; however, photo-induced epilepsy is only of concern for LED lamps under some failure modes.[46] Moreover, as suggested by ICNIRP, there is insufficient evidence (e.g., medical studies of the health impacts of flicker from LED lights) on contributing factors, affected populations, conditions, and product characteristics posing risks, and you have not provided adequate evidence to address these insufficiencies. Moreover, our understanding is that standards organizations have ongoing efforts to further evaluate flicker and, to the extent there are any health risks, such standards might sufficiently address them. The development/revision of lighting standards, and history of the lighting industry addressing issues with flicker in fluorescent lighting, support this view. For instance, existing standards and efforts appear to have addressed concern with low-frequency flicker (e.g., < 80 HZ).

  FDA finds the information provided insufficient to demonstrate the need to restrict square wave/digital flicker and/or pulse width modulation of LED lights to protect public health and safety from electronic product radiation.

2. Response to CP2

CP2 requests that FDA issue regulations to regulate electromagnetic radiation in the visible portion of the spectrum emitted by products that use LEDs that pulse, flash, or strobe ("LED flashing lights") and that these regulations set restrictions on spatial non-uniformity, chip-level peak luminance and peak radiance, spectral power distribution, synchronous and asynchronous flash rates, and rise and decay characteristics, to protect public health. Our evaluation in Section V.b.1 of the scientific and technical information provided in support of

[46] ICNIRP 2020 Statement at 555.

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restrictions on spatial non-uniformity, chip-level peak luminance and peak radiance, and spectral power distribution of LED lights, and our conclusions regarding these restrictions, also apply to LEDs that pulse, flash, or strobe. We discuss your request for restrictions on synchronous and asynchronous flash rates, and rise and decay characteristics, below. We note that CP3 also requests restrictions on these characteristics, and therefore have considered as a whole the relevant information provided for both petitions about these characteristics.

In CP2, you assert that LED strobing lights have negative effects on human health, including "nausea, panic attacks, seizures, reduced cognitive functioning, and possible eye injury" (CP2 at 14). In support of these requests, you provided a scientific review published by the Epilepsy Foundation[47] and highlight the opening line in the abstract: "[l]ight flashes, patterns, or color changes can provoke seizures in up to 1 in 4000 persons" (CP2 at 5). However, section 8.6 of the article states that a "PubMed search on January 25, 2021 using search terms 'light emitting diode' and seizures produced only five results, none of which indicated provocation of seizures and two based on animal models, showing suppression of seizure-like activity with LEDs…. The effect of LEDs on people with epilepsy is a subject that would benefit from additional research." Accordingly, FDA finds that the article does not support your claim that LED strobe lights can pose a significant risk to people with photosensitive epilepsy and synchronous and asynchronous flash rates, and rise and decay must be regulated by the FDA in order to protect the public health and safety. You also provided a diagram by IEEE[48] to support a claim that LED strobe lights would likely trigger seizures regardless of the flash rate. FDA disagrees, and the diagram does not support your claim. Instead, it shows that the greatest risk of photosensitive seizures in individuals with photosensitive epilepsy occurs in limited frequencies of slow/visible flicker. FDA acknowledges that photosensitive seizures might be triggered due to slow/visible flickering artifacts under certain circumstances for a specific subset of the population.[49] However, slow flicker generally is not encountered in modern lighting. In short, you provided no evidence to support a public health or safety concern related to rise and decay characteristics of electronic product radiation emitted by flashing or strobing LED lights.

FDA has determined that the information provided in support of CP2 is insufficient to demonstrate a performance standard to control the emission of electronic product radiation from LED flashing lights with restrictions on spatial non-uniformity, chip-level peak luminance and peak radiance, dispersion characteristics, spectral power distribution, digital flicker, and pulse width modulation is necessary at this time for the protection of the public health and safety.

3. Response to CP3

CP3 requests that FDA issue regulations to regulate electromagnetic radiation in the

[47] Fisher 2022.
[48] IEEE 1789-2015, "Recommended Practices for Modulating Current in High-Brightness LEDs for Mitigating Health Risks to Viewers." Available at: https://ieeexplore.ieee.org/document/7118618.
[49] See e.g., Wilkins, Arnold, Jennifer Veitch, and Brad Lehman. "LED lighting flicker and potential health concerns: IEEE standard PAR1789 update." 2010 IEEE Energy Conversion Congress and Exposition. IEEE, 2010.

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visible portion of the spectrum emitted by LED products used on vehicles,[50] and that these regulations set restrictions on spatial non-uniformity, chip-level peak luminance and peak radiance, dispersion characteristics, spectral power distribution, digital flicker, pulse width modulation, synchronous and asynchronous flash rates, and rise and decay characteristics, to protect public health and safety. We reference Section V.b.1 for our evaluation of scientific information provided to support restrictions on spatial non-uniformity, chip-level peak luminance and peak radiance, and spectral power distribution of LED lights and Section V.b.2 for our evaluation of the information provided about synchronous and asynchronous flash rates, and rise and decay characteristics, as the discussions in those sections also apply to LEDs used for vehicle lights. We discuss your request for restrictions on dispersion characteristics in this section. We note that CP4 also requests restrictions on dispersion characteristics and have considered as a whole the relevant information provided for both petitions about this characteristic.

CP3 and CP4 request that FDA establish regulations for LED that set restrictions on dispersion characteristics. You state that "light emitted by LEDs does not gently disperse following an inverse square law, but instead diverges slowly, maintaining its peak intensity even at long distances" (CP3 at 14, and CP4 at 14), and you include LEDs in a hazard category comparable to lasers (see in Table 1 of CP3 and Table 1 of CP4). FDA finds no support for this hazard categorization. This finding is consistent with international standards organizations such as ICNIRP, which in its ICNIRP 2020 Statement suggests applying safety standards for lamps, not lasers, to LEDs. Similarly, internationally accepted consensus standards on photobiological safety of lamps, such as IEC 62471:2006, cover LED sources as well as traditional lamps, but excludes lasers. Such standards assess the light source at a close distance. If the lamp is photobiologically safe at a close distance condition, it is safe for any other general use conditions. You provided no other scientific information to support the claim that a lack of dispersion in LED vehicle lights causes injury to human health.

You assert that LED headlights cause "blinding glare" (CP3 at 4). Although there may be glare from LED vehicle lights, you provided no scientific evidence of the effects of glare caused by LED electronic product radiation on human health, as previously noted in Section V.b.1. Moreover, the Martinsons Handbook you provided states: "[g]lare is a source of indirect hazards, which are not caused by the light itself".[51]

FDA has determined that the information provided in support of CP3 is insufficient to demonstrate a performance standard to control the emission of electronic product radiation by LED products that use LEDs that are used on vehicles, with restrictions on spatial non-uniformity, chip-level peak luminance and peak radiance, dispersion characteristics, spectral power distribution, digital flicker, pulse width modulation, synchronous and asynchronous flash rates, and rise and decay characteristics, is necessary at this time for the protection of the public health and safety.

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[50] CP3 defines at page 3 LEDs that are used on vehicles to include headlamps, taillights, brake lights, turn signals, flashing lights, Daytime Running Lights, backup lights, and all other external light sources on vehicles.
[51] Martinsons, Handbook at 3.

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4. *Response to CP4*

CP4 requests that FDA issue regulations to regulate electromagnetic radiation in the visible portion of the spectrum emitted by products that use LEDs for street lighting, and that these regulations set restrictions on spatial non-uniformity, chip-level peak luminance and peak radiance, dispersion characteristics, spectral power distribution, digital flicker, and pulse width modulation, to protect public health and safety. We reference Section V.b.1 for our evaluation of information provided to support restrictions on spatial non-uniformity, chip-level peak luminance and peak radiance, and spectral power distribution of LED lights, and Section V.b.3. for our evaluation of information provided to support restrictions on dispersion characteristics of LED lights, as these discussions also apply to LEDs used for streetlighting. FDA has determined that the information provided in support of CP4 is insufficient to demonstrate a performance standard to control the emission of electronic product radiation by products that use LEDs for street lighting with restrictions on spatial non-uniformity, chip-level peak luminance and peak radiance, dispersion characteristics, spectral power distribution, digital flicker, and pulse width modulation is necessary for the protection of the public health and safety.

In addition to your request for a performance standard for LED streetlights, you state that "LED street lights emit a visible radiation type that is unregulated, is a recognized hazard, and which does not provide safe, uniform illumination, [and therefore] LED street lights are a defective product" under 21 CFR 1003.2(b) (CP4 at 13). FDA regulation at 21 CFR 1003.2 defines when an electronic product is considered to have a defect which relates to the safety of use by reason of the emission of electronic product radiation. It is used in connection with regulatory actions against particular defective radiation-emitting products; it is not intended to be applied to an entire category of products. You provided no information (e.g., test reports) that any particular LED streetlight, as result of its design, production or assembly, emits electronic product radiation unnecessary to the accomplishment of its primary purpose, which creates a risk of injury, including genetic injury to any person, which is required for there to be a defect for the purposes of part 1003 (see also section 535 of the FD&C Act).

c. <u>FDA Found No Scientific Literature Demonstrating at this Time the Need for Regulations to Control Electromagnetic Radiation in the Visible Portion of the Spectrum Emitted by Products that Use LEDs to Protect the Public Health and Safety Requested by the Petitions</u>

FDA engaged an independent, third-party organization to conduct a comprehensive literature search and systematic review to identify the current state of knowledge with regard to adverse health effects of LED light on humans. The systematic review was guided by key questions, including: does exposure to nontherapeutic LED light elicit adverse health effects? Have particular mechanisms been identified for such manifestations? Are there characteristics of the LED device itself, or the light it emits, that may predict, increase, or decrease the likelihood and/or severity of a response? Peer-reviewed clinical and engineering literature was searched for evidence related to adverse health effects of LED light. Potential health effects of interest that were considered included but were not limited to: behavioral, neurologic, physiological (including skin and eye), and psychological effects. The review concluded that the overall

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quality of evidence in the literature for any health effects was low. Many of the studies had one or more of the following limitations: lack of randomization, single-arm study design, small sample sizes, no comparison of LED to other forms of lighting with the same attributes (e.g., illuminance or color temperature), inconsistent information on the LED attributes (e.g., intensity, luminance), and/or relatively brief experimental sessions. The literature either did not report severe adverse health effects when using LED lighting, or the results were inconclusive/inconsistent. Based on this assessment, FDA has determined that insufficient evidence exists in the literature to demonstrate that a performance standard to control the emission of electronic product radiation by products that use LEDs is necessary at this time for the protection of the public health and safety.

VI. Conclusion

For the reasons set forth above and in accordance with 21 CFR 10.30(e), FDA is denying the requests in CP1, CP2, CP3, and CP4 to establish performance standards regulating electromagnetic radiation in the visible portion of the spectrum emitted by products that use light emitting diodes (LEDs) generally, that pulse, flash, or strobe, that are used on vehicles, and that are used for street lighting.

FDA takes safety concerns regarding electronic product radiation seriously. FDA has been and continues to monitor impacts to public health and safety from radiation-emitting products consistent with our jurisdiction.

If you have any questions about this response, please contact Patricia Kaufman at patricia.kaufman@fda.hhs.gov or (301) 796-1174

Sincerely,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2024.05.24 16:58:04 -04'00'

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Deputy Center Director for Policy
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