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**ORIGINAL
FILED**

AUG 05 2024

4 THE UNITED STATES DISTRICT COURT
CLERK U.S. DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA
BY _____ DEPUTY CLERK
5 FOR THE EASTERN DISTRICT OF CALIFORNIA
6 SACRAMENTO DIVISION

8 MARK BAKER,

9 Plaintiff,

10 vs.

11 U.S. DEPARTMENT OF HEALTH AND

12 HUMAN SERVICES, ET AL.,

13 Defendants

Case No.: 2:24-CV0278-KJM DB PS

PLAINTIFF RESPONSE TO DEFENDANT'S
MOTION TO DISMISS AND REQUEST
FOR SUMMARY JUDGMENT

14
15 **I. INTRODUCTION**

- 16 1. On January 22, 2024, Plaintiff Mark Baker ("Plaintiff"), filed suit against the United States
17 Health and Human Services and its implementing agency, the Food and Drug
18 Administration ("FDA"), for failing to comply with all six sections of 21 U.S.C. 360ii(a)
19 for Light Emitting Diode products. Collectively, these six sections define the requirements
20 for the establishment of an electronic product radiation control program which is a non-
21 discretionary program that Congress has directed the FDA to establish and carry out. (21
22 U.S.C. 360ii).
- 23 2. In their response to Plaintiff's complaint, the FDA focuses exclusively on the FDA's
decision to not publish performance standards for LED products, which is required by 21

1 U.S.C. 360ii(a)(1) and 21 U.S.C. 360ii(a)(6)(B). However, the FDA’s focus on just
2 performance standards ignores the primary purpose of 21 U.S.C. 360ii and the six sections
3 of 21 U.S.C. 360ii(a), which is the establishment and implementation of an electronic
4 product radiation control program for the large class of devices that emit Visible Light
5 radiation from Light Emitting Diodes (“LEDs”). The FDA has failed to establish the
6 required radiation control program for LED products.

7 3. Plaintiff is an individual diagnosed with autism spectrum disorder and is thus a member of
8 the class of individuals with disabilities and is entitled to equal protection under the 5th
9 Amendment Equal Protection Clause. Exposure to LED light has severe neurological
10 impacts on Plaintiff due to Plaintiff’s autism disability. In their response, the FDA claims
11 that the FDA’s inaction on regulating LED products excuses the FDA from having to
12 provide protection from harm from LEDs for Plaintiff. In truth, the FDA has not practiced
13 inaction, but has willfully and deliberately chosen to ignore the impacts of LED light on
14 individuals with neurological disabilities, has not engaged in reasoned decision making in
15 violation of the Administrative Procedure Act (“APA”), and thus the FDA has violated
16 Plaintiff’s 5th Amendment right to equal protection.

17 18 **II. ADMINISTRATIVE REMEDIES**

19 4. Plaintiff is President of the Soft Lights Foundation, a 501(c)(3) nonprofit dedicated to
20 protecting individuals from the harms of LED light. Under the Administrative Procedure
21 Act, the Soft Lights Foundation submitted four separate regulatory petitions to the FDA to
22 comply with 21 U.S.C. 360ii (FDA-2022-P-1151, FDA-2023-P-0233, FDA-2023-P-3828,
23 and FDA-2023-P-3879), with the first petition having been submitted on June 13, 2022.

1 For each petition, the FDA responded with similar letters, each of which contained the
2 same boilerplate statement, “FDA has been unable to reach a decision on your petition
3 because it raises issues requiring further review and analysis by agency officials.”
4 (EXHIBIT A). The FDA provided no reasoning or justification as to why the FDA was
5 unable to reach a decision as to whether the FDA should comply with 21 U.S.C. 360ii. The
6 FDA also did not provide any information as to what difficulties the FDA was
7 encountering or a timeline for when the FDA’s final decision might be made. Due to the
8 lack of transparency by the FDA, Plaintiff filed this lawsuit on January 22, 2024, to compel
9 the FDA to comply with 21 U.S.C. 360ii for LED products.

- 10 5. On May 24, 2024, likely as a result of Plaintiff’s lawsuit, the FDA issued a final decision
11 and denied all four petitions. However, as discussed in more detail below, the FDA’s final
12 decision is not based on reasoned decision making, as required by the APA.

13 **III. DISOLUTION OF TEPRSC**

- 14
15 6. The US Department of Energy states that LEDs are a “radically new technology” that emit
16 a “directional” light with “unique characteristics.”¹ It should be immediately obvious from
17 the use of such strong language that the FDA should have been, and still must be,
18 intimately and deeply involved with regulation of LED products which are such a radically
19 new technology.
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¹ https://www1.eere.energy.gov/buildings/publications/pdfs/ssl/ssl_lessons-learned_2014.pdf

- 1 7. The Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) was
2 established by the 1968 Radiation Control for Health and Safety Act. 21 U.S.C.
3 360kk(f)(1)(A) states, “The Secretary shall establish a Technical Electronic Product
4 Radiation Safety Standards Committee (hereafter in this part referred to as the
5 “Committee”) which he shall consult before prescribing any standard under this section.”
6 As per the FDA, the committee is a non-discretionary Federal advisory committee
7 established to provide advice and consultation to the Commissioner.²
- 8 8. TEPRSSC is required to consist of 15 members, with five from industry, five from the
9 government, and five from the general public. Despite the non-discretionary requirements
10 for this committee, the FDA has deliberately allowed TEPRSSC to dissolve. There are
11 currently 11 vacancies out of the 15 positions, there is no chairperson, and the last time that
12 TEPRSSC met was in 2016.^{3,4}
- 13 9. 21 U.S.C. 360kk(f)(1)(B) states, “The [TEPRSSC] Committee may propose electronic
14 product radiation safety standards to the Secretary for his consideration. All proceedings of
15 the Committee shall be recorded and the record of each such proceeding shall be available
16 for public inspection.” However, since the FDA allowed TEPRSSC to become defunct in
17 2016, for the evaluation of the four Soft Lights Foundation petitions to regulate LED
18 products, the FDA contracted with a single individual to perform a literature review. It is
19 worth pausing here to reflect on the magnitude of what FDA has done. Congress has made

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22 ² <https://www.federalregister.gov/documents/2023/01/24/2023-01219/advisory-committee-technical-electronic-product-radiation-safety-standards-committee-renewal>

23 ³ <https://www.fda.gov/advisory-committees/technical-electronic-product-radiation-safety-standards-committee/roster-technical-electronic-product-radiation-safety-standards-committee>

⁴ [Past Meeting Materials, Technical Electronic Product Radiation Safety Standards Committee | FDA](#)

1 clear that the FDA is required to consult with TEPRSSC on matters involving
2 electromagnetic radiation, and that the TEPRSSC discussions shall be made public. These
3 well thought-out, non-discretionary mandates provide transparency and well-reasoned
4 decision-making for the complex topic of protecting the public from the harms of
5 electromagnetic radiation.

6 10. However, in its decision to not publish performance standards for LED products, the FDA
7 did not rely on the expertise of the Congressionally mandated TEPRSSC advice, and
8 instead relied solely on a single individual whose identity and qualifications the FDA has
9 chosen to keep secret. Instead of recording the meetings that would have been held by 15
10 members of TEPRSSC, the entire evaluation process for the four Soft Lights Foundation
11 petitions was done in secret by a single individual, and neither Plaintiff, nor the public, nor
12 Congress has been provided the transparency that Congress required when passing the
13 1968 Radiation Control for Health and Safety Act.

14 11. High-powered LED products started to enter the environment around the year 2000. It was
15 around the year 2016 when there was a dramatic increase in high-intensity LED lights,
16 especially those LED lights with extreme blue wavelength light, began appearing in car
17 headlights, streetlights, light bulbs, and flashing lights on police cars and fire trucks. At the
18 exact time when TEPRSSC should have been meeting almost daily to advise FDA officials
19 on actions that needed to be taken to protect public health and safety from LED Visible
20 Light radiation, the FDA chose instead to dissolve TEPRSSC. This action by FDA
21 officials was grossly negligent, and a violation of the of the non-discretionary requirements
22 of 21 U.S.C. 360kk(f).

1 12. Without having the advice of TEPRSSC, and without having established a radiation control
2 program for LED products, the FDA has been doing nothing to ensure the health and safety
3 of the public from the harms of LED light. Upon receipt of the four Soft Lights Foundation
4 petitions to regulate LED products, the FDA turned to an unnamed, unqualified third party
5 to review some of the existing literature. This is not the structure that Congress created via
6 the 1968 Radiation Control for Health and Safety Act. Congress mandated that the
7 Technical Electronic Product Radiation Safety Standards Committee consist of
8 stakeholders with expertise in various areas to advise the FDA involving LED products,
9 including how to minimize exposure to, and emissions of, LED light, how to establish what
10 characteristics or levels of LED light are unnecessary, and what performance standards are
11 necessary to protect public health and safety. The FDA’s dissolution of TEPRSSC and
12 elimination of the advice of the committee experts is a violation of 21 U.S.C. 360kk(f).
13 The APA, in 5 U.S.C. 706(2)(D), states, “The reviewing court shall hold unlawful and set
14 aside agency action, findings, and conclusions found to be without observance of procedure
15 required by law.”

16 **IV. 360ii PROGRAM OF CONTROL**

17 13. 21 U.S.C. 360ii establishes the program of control for regulation of electromagnetic
18 radiation from electronic products. 21 U.S.C. 360ii(a) states:

19 **§360ii. Program of control**

20 **(a) Establishment**

21 The Secretary shall establish and carry out an electronic product radiation control
22 program designed to protect the public health and safety from electronic product
23 radiation. As a part of such program, he shall –

1 14. The term ‘shall’ in the paragraph above means that Congress mandates that these actions be
2 carried out by the Secretary of Health and Human Services (“HHS”) and its implementing
3 agency, the Food and Drug Administration (“FDA”). A mandate from Congress means
4 that the action is non-discretionary. Thus, 21 U.S.C. 360ii(a) mandates that the FDA
5 MUST establish and carry out an electronic product radiation control program designed to
6 protect public health and safety from electronic product radiation.

7 15. Light Emitting Diodes (“LEDs”) are an electronic product that emit electromagnetic
8 radiation in the Visible Light (“VL”) part of the electromagnetic spectrum. Therefore, the
9 Secretary of Health and Human Services and it’s implementing agency the Food and Drug
10 Administration, has a **non-discretionary requirement** to establish and carry out a
11 radiation control program designed to protect public health and safety from the Visible
12 Light radiation emitted by LEDs. (“LED light”).

13 16. However, the FDA has not established and is not carrying out a radiation control program
14 for LED products, in direct violation of 21 U.S.C. 360ii. The FDA’s Motion to Dismiss
15 attempts to deflect the Court’s attention away from this fact, by falsely claiming that LED
16 products are inherently safe and by falsely inferring that it is incumbent on Plaintiff to
17 conclusively demonstrate that LED products are not safe. The legal issue for the Court to
18 determine is not the technical details of whether LED products are safe or not, but whether
19 the FDA has established and is properly carrying out a radiation control program for LED
20 products as required by 21 U.S.C. 360ii. The evidence presented in the original claim and
21 further demonstrated in the paragraphs below prove that the FDA has not established a
22 radiation control program for LED products and is thus violating the law.

1 17. 21 U.S.C. 360ii(a) contains six parts that establish the elements of the radiation control
2 program for LED products. The FDA has not implemented any of these elements, and as a
3 result, the FDA has not established a radiation control program for LED products. Below
4 is a summary of each of the six required elements for a radiation control program for LED
5 products.

6 18. **21 U.S.C. 360ii(a)(1)** - *“Pursuant to section 360kk of this title, develop and administer*
7 *performance standards for electronic products”*. The FDA has acknowledged that the
8 FDA has not published any performance standards for LED products. The FDA claims that
9 publication of performance standards for LED products is discretionary. However, a
10 federal agency is not permitted to act arbitrarily and capriciously in making their decisions,
11 as is the case by the FDA here. The FDA has provided no evidence that LED products
12 manufactured since the turn of the millennium are photobiologically, neurologically,
13 psychologically, and hormonally safe for all individuals, and yet the FDA states that no
14 performance standards are necessary. The FDA has not set any limit on the intensity of
15 LED products to ensure photobiological safety. For example, LED intensity is measured
16 using the metric ‘radiance’, which is the same metric as used with lasers. At what radiance
17 does an LED cause eye damage? 1 W/sr¹/m²? 10 W/sr¹/m²? 100 W/sr¹/m²? 1,000,000
18 W/sr¹/m²? The FDA has offered no opinion. The FDA has not demonstrated that all
19 spectral power distribution characteristics of LED products are always safe. The FDA has
20 not demonstrated that all forms of digital flicker are always safe. The FDA has not
21 established the guardrails for any LED product, and only by acting arbitrarily and
22 capriciously is the FDA able to claim that no performance standards are required for all
23 LED products.

1 19. **21 U.S.C. 360ii(a)(2)** – “*Plan, conduct, coordinate, and support research, development,*
2 *training, and operational activities to minimize the emissions of and the exposure of people*
3 *to, unnecessary electronic product radiation*”. The FDA has not developed a plan to
4 minimize the emissions of LED products. The FDA has not developed a plan to minimize
5 exposure of people to LED light. The FDA has not defined the metrics for the levels and
6 characteristics of LED light that are necessary and the levels and characteristics of LED
7 light that are unnecessary. The FDA is not conducting any operational activities to
8 minimize LED product emissions. The FDA is not conducting any operational activities to
9 minimize human exposure to LED light. The FDA is not coordinating any research,
10 development, training or operational activities to minimize LED product emissions. The
11 FDA is not coordinating any research, development, training or operational activities to
12 minimize exposure to LED light. The FDA is not supporting any research, development,
13 training or operational activities to minimize LED product emissions. The FDA has
14 dissolved the Technical Electronic Product Radiation Safety Standards Committee. The
15 FDA is taking none of the required actions that are essential to a radiation control program
16 for LED products.

17 20. **21 U.S.C. 360ii(a)(3)** – “*Maintain liaison with and receive information from other Federal*
18 *and State departments and agencies with related interests, professional organizations,*
19 *industry, industry and labor associations, and other organizations on present and future*
20 *potential electronic product radiation.*” The FDA does not maintain a liaison with any
21 other federal agency and does not receive information from any other federal agency or
22 State Department or agency related to electronic product radiation from LEDs. The FDA
23 does not maintain a liaison with professional organizations such as the Illuminating

1 Engineering Society, American Medical Association, or the Conference of Radiation
2 Control Program Directors related to minimizing exposure to, and emissions of, LED light.
3 The FDA does not maintain a liaison with General Motors, Acuity Brands, or Whelen
4 Engineering to share information on present and future LED levels of electromagnetic
5 radiation emitted by LEDs. The FDA does not maintain a liaison with the United Auto
6 Workers, United Federation of Teachers, or the International Association of Fire Fighters
7 to ensure worker safety when exposed to LED light. The FDA is not engaged with any of
8 these entities, even though such engagement is mandated by law and is an essential part of
9 a radiation control program for LED products.

10 21. **21 U.S.C. 360ii(a)(4)** – *“Study and evaluate emissions of, and conditions of exposure to,*
11 *electronic product radiation and intense magnetic fields.”* The FDA is not studying
12 emissions from LED products. The FDA is not evaluating emissions from LED products.
13 The FDA is not studying or evaluating conditions of exposure to LED products such as
14 LED vehicle headlights, LED streetlights, and LED flashing lights. LED products are
15 rapidly evolving, and yet the FDA has no radiation control program in place for studying
16 the emissions of and conditions of exposure to these LED products.

17 22. **21 U.S.C. 360ii(a)(5)** – *“Develop, test, and evaluate the effectiveness of procedures and*
18 *techniques for minimizing exposure to electronic product radiation.”* The FDA has not
19 developed, tested, or evaluated the effectiveness of any procedure or technique for
20 minimizing exposure to LED light. The public is being exposed to whatever intensity,
21 whatever spectral power distribution, whatever digital flicker, and whatever spatial
22 distribution of LED light that is emitted by LED vehicle headlights, LED flashing lights,
23 and LED light bulbs, that are sold by the manufacturers. The FDA has done nothing to

1 develop, test, or evaluate the effectiveness of any procedure or technique for minimizing
2 the public’s exposure to LED light, even though this is a required element of a radiation
3 control program for LED products.

4 23. **21 U.S.C. 360ii(a)(6)** – “*consult and maintain liaison with the Secretary of Commerce, the*
5 *Secretary of Defense, the Secretary of Labor, the Atomic Energy Commission, and other*
6 *appropriate Federal departments and agencies on (A) techniques, equipment, and*
7 *programs for testing and evaluating electronic product radiation, and (B) the development*
8 *of performance standards pursuant to section 360kk of this title to control such radiation*
9 *emissions.” The only federal agency with the authority and mandate to implement a*
10 *radiation control program for LED products is the FDA. Therefore, all other federal*
11 *agencies are dependent on the FDA consulting and maintaining a liaison with the other*
12 *federal agencies for testing and evaluating emissions from LED products and for the*
13 *development and publication of performance standards for LED products. NHTSA is*
14 *dependent on the FDA for the development and publication of performance standards for*
15 *LED vehicle headlights. The DOE is dependent on the FDA for development and*
16 *publication of performance standards for LED streetlights and LED light bulbs. The EPA*
17 *is dependent on the FDA for the development and publication of performance standards for*
18 *controlling unnecessary electromagnetic Visible Light radiation from LED products (also*
19 *known as “light pollution”). OSHA is dependent on the FDA for the development and*
20 *publication of performance standards for protecting worker safety from exposure to LED*
21 *lights. The Access Board is dependent on the FDA for the development and publication of*
22 *performance standards for LED products to ensure civil rights protections and compliance*
23 *with the Americans with Disabilities Act. The FAA is dependent on the FDA for the*

1 development and publication of performance standards for LEDs used at airports and on
2 aircraft. Yet, the FDA is not consulting with or maintaining a liaison with any of these
3 federal agencies and has not published any performance standards for any LED product,
4 despite this non-discretionary requirement which is part of the radiation control program
5 for LED products.

6 24. The FDA has failed to implement a radiation control program for LED products, in
7 violation of 21. U.S.C. 360ii, and thus Defendant’s Motion to Dismiss should be denied.

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V. REPORTS OF HARM

10 25. In April 2024, the Soft Lights Foundation began collecting reports of harm due to exposure
11 to LED light from members of the public (APPENDIX B). The Soft Lights Foundation has
12 been submitting these reports to the FDA once per month. However, since the FDA has
13 not established a radiation control program for LED products as required by 21 U.S.C.
14 360ii, and because the FDA dissolved TEPRSSC, in violation of 21 U.S.C. 360kk(f), these
15 reports of harm caused by products using LEDs are being ignored.

16 26. For example, one person submitted a report of harm and stated, ‘When I am too close to
17 these white LEDs, I tend to get a large, massive migraine and then I start to lose control of
18 my senses.’ Another person wrote, ‘As I walked into my local Costco, I was assaulted by
19 an LED demonstration light.’ Another person wrote, ‘After accidentally (I have to avoid
20 exposure to the direct beam of the LED) viewing a small but powerful security light for
21 less than a second, I had to violently throw up for up to two minutes at which point I lost
22 consciousness and fell to the concrete floor and hit my head.’ These reports do not indicate
23 that LED lights are safe, as the FDA suggests.

1 27. The Soft Lights Foundation has a public petition specifically for LED headlights.⁵ Over
2 60,000 people have signed the petition, demanding protection from LED headlights. One
3 person commented, “Due to having an astigmatism in my right eye the led lights have
4 literally made it nearly impossible to drive at night.” Another person wrote, “Super bright
5 Led headlights are harmful to the eyes and super dangerous.” Another person wrote, “i get
6 migraines whenever i drive at night now.” These comments do not indicate that LED lights
7 are safe. As of July 2024, the number of comments has reached 210 pages. The Soft
8 Lights Foundation has submitted these public comments to the FDA on multiple occasions,
9 and yet because the FDA has not established a radiation control program for LED products,
10 these comments have not been investigated by the FDA.

11 28. The New York State Public Service Commission Administrative Law case 23-E-0727,
12 Complaint of MarieAnn and Richard Cherry and Others Concerning LED Street Lights in
13 the Village of Cambridge, involves the negative health impacts of LED streetlights,
14 including epileptic seizures.⁶ The public submitted 181 comments, nearly all negative. For
15 example, the petitioner wrote, “A resident with acute chronic epilepsy and migralepsy has
16 suffered hundreds of epileptic seizures and associated physical injuries caused by exposure
17 to the new LED street lights.” Another person wrote, ‘I didn’t realize other people in town
18 were having problems with the LED lights. It took me awhile to realize the impact of these
19 lights but I no longer walk that streets the have changed over to them. The light is
20 absolutely hideous.” Another person wrote, “These LEDs in contrast are stressful and
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⁵ <https://www.change.org/p/u-s-dot-ban-blinding-headlights-and-save-lives>

⁶ <https://documents.dps.ny.gov/public/MatterManagement/CaseMaster.aspx?MatterCaseNo=23-E-0727>

1 irritating. I have to stay away from them, or else I suffer headaches, nausea, and dizziness. I
2 don't go out in the village in the evening at all anymore since these awful LED lights went
3 in. The LED street lights are an encumbrance and a serious nuisance.” These comments do
4 not support the FDA’s contention that LED streetlights are safe.

5 29. Plaintiff has received two letters of support from colleagues who attest to the psychological
6 trauma Plaintiff suffers when exposed to LED lights, especially LED flashing lights, due to
7 Plaintiff’s autism. (APPENDIX C AND D).

8 30. Because the FDA has not established the required radiation control program for LED
9 products, and because the FDA is not continuously testing, researching, and evaluating
10 LED products and reports of harm, the FDA is not acting on new information as it arrives.
11 There is no indication that the FDA has assigned any staff member to investigate the
12 reports of harm that the Soft Lights Foundation has submitted. The FDA is in violation of
13 21 U.S.C. 360ii which is a non-discretionary directive to the FDA to plan, conduct,
14 coordinate, and support research, development, training, and operational activities to
15 minimize exposure to, and emissions of, LED light to protect public health and safety.

16 17 **VI. EHT v. FCC**

18 31. The case Environmental Health Trust, et al., v. Federal Communications Commission No.
19 20-1025 (D.C. Circuit 2021) (“EHT Case”) has many similarities to this lawsuit against the
20 FDA and is therefore worthy of discussion as it relates to this case.⁷ While the EHT Case
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⁷ <https://law.justia.com/cases/federal/appellate-courts/cadc/20-1025/20-1025-2021-08-13.html>

1 was a lawsuit brought against the FCC, there was significant discussion surrounding the
2 FDA's requirements to evaluate the health impacts of radiofrequency ("RF") radiation from
3 electronic products and the deference of the FCC to the FDA for their scientific expertise.

4 32. In the EHT Case, the D.C. Circuit Court ruled that the FCC, and thus the FDA, acted
5 arbitrarily and capriciously in its failure to respond to evidence that RF radiation is harmful
6 (Page 9, (II)(A)(i)).

7 33. The FDA has acted similarly on the topic of health and safety involving Visible Light
8 radiation emitted by LED products. While there are numerous reports of harm involving
9 exposure to LED lights, the FDA has acted arbitrarily and capriciously by ignoring these
10 reports of harm and by dissolving the TEPRSSC that is mandated by Congress to be
11 investigating such reports of harm.

12 34. In its decision ruling against the FCC, the D.C. Circuit Court wrote, "The Commission
13 failed to provide a reasoned explanation for its determination that its guidelines adequately
14 protect against the harmful effects of exposure to radiofrequency radiation unrelated to
15 cancer." (Page 3, Paragraph 2).

16 35. "When an agency in the Commission's position is confronted with evidence that its current
17 regulations are inadequate or the factual premises underlying its prior judgment have
18 eroded, it must offer more to justify its decision to retain its regulations than mere
19 conclusory statements. See *Am. Horse*, 812 F.2d at 6; *Am. Radio*, 524 F.3d at 241. Rather,
20 the agency must provide "assurance that [it] considered the relevant factors," and it must
21 provide analysis that follows "a discernable path to which the court may defer." *Am.*
22 *Radio*, 524 F.3d at 241." (Page 9, Paragraph 1).

1 36. “We do not agree that these statements provide a reasoned explanation for the
2 Commission’s decision to terminate its notice of inquiry. Rather, we find them to be of the
3 conclusory variety that we have previously rejected as insufficient to sustain an agency’s
4 refusal to initiate a rulemaking.” (Page 12, Paragraph 3). In its denial of the Soft Lights
5 Foundation petitions, the FDA wrote, “Some evidence suggests some individuals associate
6 health effects, like migraines, with temporal light modulation...Moreover, our
7 understanding is that standards organizations have ongoing efforts to further evaluate
8 flicker and, to the extent there are any health risks, such standards might sufficiently
9 address them.” This conclusory statement from the FDA does not provide evidence of
10 reasoned decision making, but rather shows that FDA is relying on a hope and prayer that
11 some other entity is addressing the issue of square wave flicker.

12 37. The D.C. Circuit Court wrote, “What the Commission may not do, however, is rely on an
13 outside expert’s silence or conclusory statements in lieu of some reasoned explanation for
14 its decision.” (Page 16, Paragraph 2). In the decision to deny the four Soft Lights
15 Foundation petitions, the FDA relied on the conclusory statements of a single secret outside
16 ‘expert’, rather than the 15 members of the Congressionally mandated TEPRSSC. The
17 FDA’s decision does not meet the criteria for reasoned decision making, and therefore
18 violates the requirements of the Administrative Procedure Act.

19 38. The D.C. Circuit Court wrote, “Nevertheless, an agency’s decision not to initiate a
20 rulemaking must have some reasoned basis, and an agency cannot simply ignore evidence
21 suggesting that a major factual predicate of its position may no longer be accurate.” (Page
22 17, Paragraph 1). The FDA’s decision to not initiate rulemaking for LED products lacks a
23

1 reasoned basis and ignores the overwhelming evidence of harm from exposure to LED
2 lights that has already been documented.

3 **VII. REBUTTAL TO DEFENDANT’S POINTS AND AUTHORITIES**

4 39. The following paragraphs rebut key elements of Defendant’s Points and Authorities. All
5 references are to the MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT
6 OF MOTION TO DISMISS.

7 40. POINT 1 (Page 1, Line 4): “*FDA has issued comprehensive regulations establishing an*
8 *electronic product radiation control program designed to protect the public health and*
9 *safety from electronic product radiation. 21 C.F.R. Subchapter J.*” The electronic product
10 radiation control program developed by the FDA is far from comprehensive, as the FDA
11 has failed to establish a radiation control program for the entire class of LED products.

12 41. POINT 2 (Page 1, Line 6): “*Plaintiff now brings this suit against FDA because the agency*
13 *has not promulgated performance standards for various light-emitting diode (LED)*
14 *products.*” Here, the FDA attempts to distract the Court from the core issue. It is true that
15 one of the failures of the FDA is not publishing performance standards for LED products,
16 but the claim by Plaintiff is that the FDA has not implemented ANY of the six elements
17 that are required to establish a radiation control program for LED products to ensure public
18 health and safety. 21 U.S.C. 360ii is a non-discretionary requirement for the FDA to
19 implement a radiation control program which necessarily includes a radiation control
20 program for the entire class of LED products. Issuing performance standards is just one of
21 the many actions that the FDA must take to implement a radiation control program for LED
22 products.
23

1 42. POINT 3 (Page 1, Line 11): “*Count One fails to state a claim because Plaintiff has not*
2 *identified any final agency action, nor does he identify any statutory provision compelling*
3 *the agency to promulgate performance standards for LED lights.*” This paragraph contains
4 two false statements. First, the FDA issued final actions on May 24, 2024, on all four Soft
5 Lights Foundation to regulate LED products. (FDA-2022-P-1151, FDA-2023-P-0233,
6 FDA-2023-P-3828, and FDA-2023-P-3879) and in those final actions, the FDA denied all
7 four petitions. Second, the statutory provisions compelling the FDA to publish
8 performance standards for LED products are 21 U.S.C. 360ii(a)(1) and 21 U.S.C.
9 360ii(a)(6)(B). In 21 U.S.C. 360ii(a)(1), the Secretary must publish performance standards
10 if he determines that such standards are necessary. However, the FDA may not act
11 arbitrarily or capriciously, must provide reasoned arguments, and cannot rely on conclusory
12 statements. As explained earlier, the FDA’s decision to not regulate LED products fails to
13 meet the reasoned arguments required by the APA. However, even if the FDA were able to
14 provide reasoned justification for not publishing its own performance standards, 21 U.S.C.
15 360ii(a)(6)(B) is a non-discretionary requirement for the FDA to consult and maintain a
16 liaison with other federal agencies such as NHTSA, DOE, EPA, OSHA, CPSC, Access
17 Board, and others in the development of performance standards as part of the mandatory
18 electronic product radiation control program for LED products. ONLY in consultation with
19 these other federal agencies and then ONLY using reasoned arguments, could the FDA and
20 NHTSA determine that performance standards for LED headlights are not necessary to
21 protect the public from photobiological harm, or could the FDA and DOE determine that
22 performance standards for LED streetlights are not necessary to protect the public from
23 hormonal harm, or could the FDA and Access Board determine that performance standards

1 for LED flashing lights on police cars are not necessary to protect the civil rights for
2 individuals with disabilities. The FDA has not cooperated with any other federal agency to
3 make reasoned determinations that publication of performance standards for LED products
4 are not necessary, nor has the FDA cooperated with other federal agencies to publish those
5 performance standards that are determined to be necessary.

6 43. POINT 4 (Page 1, Line 16): “*Counts Two and Three fail to state a claim because they do*
7 *not satisfy the elements of an equal protection violation.*” Defendant presents no evidence
8 to support this point. The FDA’s decision to not establish a radiation control program for
9 LED products has segregated the public into two groups. The first group, without
10 disabilities, may have a level of tolerance of LED light so as not to suffer acute harm from
11 exposure to LED lights. The second group, which includes Plaintiff and individuals with
12 neurological disabilities, are unable to tolerate the light emitted by many LED products and
13 suffer acute reactions such as non-epileptic and epileptic seizures, migraines, panic attacks,
14 vomiting, and thoughts of suicide. By failing to establish a radiation control program for
15 LED products and by failing to initiate cooperation with other federal agencies to publish
16 performance standards for LED products to ensure protection of the second group, the FDA
17 has violated Plaintiff’s constitutional right to equal protection.

18 44. POINT 5 (Page 2, Line 8): “*Pursuant to the Radiation Control provisions, FDA has*
19 *established an electronic product radiation control program.*” The FDA has not
20 established an electronic product radiation control program for LED products, which is the
21 issue for this case. The FDA cannot justifiably claim that it has established an electronic
22 product radiation control program which ignores an entire class of electromagnetic
23 radiation emitting products that have been shown to be unsafe. Congress passed the

1 Radiation Control for Health and Safety Act in 1968 to ensure protection of public health
2 and safety after decades of invention of new electronic products (e.g. x-ray machines,
3 television sets, lasers, Light Emitting Diodes, etc.) showed to Congress that
4 electromagnetic radiation can cause serious harm to public health and safety. The FDA's
5 decision to simply ignore the impacts of Visible Light radiation emitted by LEDs is
6 arbitrary and capricious and a violation of the 1968 Radiation Control for Health and
7 Safety Act which directs the FDA to minimize emissions of, and exposure to,
8 electromagnetic radiation to protect public health and safety.

9 45. POINT 6 (Page 2, Line 10): *“As part of that program, FDA conducts certain operational*
10 *activities related to electronic products to ‘minimize the emissions of and the exposure of*
11 *people to, unnecessary electronic product radiation.’ 21 U.S.C. § 360ii(a). These activities*
12 *include “plan[ning], conduct[ing], coordinat[ing], and support[ing] research,*
13 *development, training, and [other] operational activities.”* The FDA is conducting no
14 operational activities for LED products and is not planning, conducting, coordinating or
15 supporting research, development, training or other operational activities for LED products.
16 The FDA has not implemented a radiation control program for LED products to minimize
17 the emissions of, and exposure to, unnecessary LED Visible Light Radiation. In fact, the
18 FDA has not even established the criteria for what LED light is necessary and what LED
19 light is unnecessary.

20 46. POINT 7 (Page 2, Line 15): *“In addition, Section 360kk of the Radiation Control*
21 *provisions requires FDA to develop and administer performance standards for electronic*
22 *products if the agency “determines that such standards are necessary for the protection of*
23 *the public health and safety.”* The phrase “if the agency determines that such standards are

1 necessary” requires the FDA to perform a comprehensive analysis and to make a reasoned
2 determination. It is not sufficient for the FDA to hire one secret outside contractor to
3 review a handful of research papers on the topic of LEDs. As part of the radiation control
4 program for LED products, the FDA is required to test, evaluate, research, study, liaise
5 with other agencies, review, staff, and maintain an ongoing operation to ensure that the
6 relentless inventing of new LED products does not put public health and safety at risk.
7 Instead, the FDA has failed to carry out any of these actions and has arbitrarily and
8 capriciously claimed that performance standards for LED products are not necessary by
9 using conclusory reasoning.

10 47. POINT 8 (Page 2, Line 21): *“Due to a long history of safety with respect to LED products*
11 *and the visible wavelengths they emit, FDA has not found performance standards to*
12 *control the radiation from LED products to be necessary for the protection of the public*
13 *health and safety.”*. The FDA has provided no evidence to support the claim that LED
14 products have a long history of safety. However, even if we were to believe that LED
15 products had previously been safe long ago, there is no reason to believe that LED products
16 are currently safe or will be safe in the future. The purpose of the Radiation Control for
17 Health and Safety Act is to ensure that the FDA is continuously studying the impacts of
18 electromagnetic radiation on human health and safety, and establishing the necessary
19 performance standards to ensure that the public is protected from emissions of, and
20 exposure to, unnecessary electromagnetic radiation.

21 48. When the Light Emitting Diode was first invented in the 1960s, the light was only red and
22 the intensity so dim that it often required a magnifying glass to view the light emitted by
23 the LED. Now, in 2024, the light emitted by a tiny LED chip is so powerful, and often

1 emitting photobiologically and hormonally hazardous blue wavelength light, that LEDs are
2 a photobiological, neurological, psychological, and hormonal health hazard.

3 49. There was a moment in time, in the late 1990s and early 2000s, where LED products went
4 from generally safe to dangerous. For example, in 2005, Andrew Dennington of Carclo
5 Technical Plastics, while presenting a series of optical design tips stated, “**The latest**
6 **generation of LEDs is not safe, and someone will have their eyes damaged by a high-**
7 **power LED product,**”⁸ The “long history of safety” for LED products, if such safety ever
8 existed at all, ended at the start of this millennium, and the FDA’s reliance on the past
9 history of LED safety has no bearing on the safety of LEDs manufactured since
10 approximately the year 2000.

11 50. Defendant writes, “FDA has not found performance standards to control the radiation from
12 LED products to be necessary for the protection of the public health and safety.” *Id.* This is
13 a conclusory statement that does not meet the requirements of reasoned decision making.
14 In order to “find” something, it is necessary to “look”. Because the FDA has failed to
15 establish a radiation control program for LED products, the FDA is not looking for any
16 evidence that shows that LED products require performance standards. In truth, the
17 evidence is overwhelming that LED products require the publication of performance
18 standards.

19 51. POINT 9 (Page 2, Line 25): “*Moreover, FDA generally does not consider it necessary to*
20 *issue specific performance standards for every type of electronic product because most*
21 *such products do not pose a risk to public health, and because of the effectiveness of*
22

23

⁸ <https://www.ledsmagazine.com/smart-lighting-iot/smart-cities/article/16696386/leds-are-safe-fact-or-fiction>

1 *existing mitigations and alternative approaches to protect public health including*
2 *'manufacturers' voluntary compliance with consensus standards' and 'applicability of*
3 *other types of controls.'"* This is a shocking statement by the FDA. After decades of new
4 electronic products causing harm to public health and safety appeared in the first half of the
5 1900s, Congress passed the 1968 Radiation Control for Health and Safety Act which
6 directs the FDA minimize the emissions of, and exposure to, unnecessary electromagnetic
7 radiation from electronic products. Congress did not state that most electronic products do
8 not pose a health risk to the public. Congress found the opposite, which is that all
9 electromagnetic radiation poses a risk to public health. 21 U.S.C. 360ii is carefully crafted
10 to ensure that the FDA is continuously testing and evaluating emissions from electronic
11 products to ensure that these products are not causing harm. In no manner did Congress
12 authorize the FDA to take the position that the electromagnetic radiation emitted by
13 electronic products is harmless or even generally safe. Congress directed the FDA to
14 assertively minimize exposure to, and emissions of, unnecessary electromagnetic radiation.
15 The only way for the FDA to comply with this directive from Congress is for the FDA to
16 establish a comprehensive radiation control program, which would include a radiation
17 control program for the entire class of LED products. The radiation control program for
18 LED products would first establish the criteria for the difference between 'necessary' and
19 'unnecessary' LED light. The LED radiation control program would also establish limits
20 on intensity, spatial distribution, spectral power distribution, square wave flicker, and
21 flashing characteristics for LED products.

22 52. The FDA writes, "*because of the effectiveness of existing mitigations and alternative*
23 *approaches to protect public health including 'manufacturers' voluntary compliance with*

1 *consensus standards’ and ‘applicability of other types of controls.’* The FDA provides no
2 evidence that there are ANY mitigations or alternative approaches to minimizing the
3 emissions of, and exposure to, LED light. The industry has no limits on intensity. The
4 industry has zero standards for emissions of or exposure to blue wavelength light. The
5 industry has zero standards for spatial uniformity. The industry has zero standards for LED
6 flashing light characteristics that would protect individuals from seizures or migraines. The
7 idea that the industry can self-police is unfounded. Congress did not pass the 1968
8 Radiation Control for Health and Safety Act so that the FDA could then claim that the
9 industry can voluntarily comply with non-existent consensus standards. Congress directed
10 the FDA to establish a comprehensive radiation control program for electromagnetic
11 radiation emitted by electronic products. Rather than implementing such a program for
12 LED products, the FDA has allowed industry to invent and sell LED products entirely
13 unimpeded by concern for public health and safety. Again, the FDA provides no evidence
14 to support that there are any ‘existing mitigations’ or ‘alternative approaches’ or that
15 industry has developed any ‘consensus standards’ for spatial uniformity, blue wavelength
16 light, square wave flicker, intensity limits, or flashing characteristics. This wishful
17 thinking by the FDA does not amount to reasoned decision making.

18 53. POINT 10 (Page 3, Line 6): *“On May 24, 2024, FDA denied those citizen petitions because*
19 *the agency found that LED performance standards are not necessary to protect the public*
20 *health. Ex. 1 at 8, 17-18. In reaching that determination, FDA comprehensively reviewed*
21 *the evidence Plaintiff submitted, and the agency even “engaged an independent, third-party*
22 *organization to conduct a comprehensive literature search and systematic review to*
23 *identify the current state of knowledge with regard to adverse health effects of LED light on*

1 *humans.*” This is another astonishing statement by the FDA. 21 U.S.C. 360ii requires the
2 FDA to test, evaluate, research, liaise with other agencies, receive reports, and take all
3 other actions necessary to ensure public health and safety from emissions of, and exposure
4 to, LED light. In this statement, the FDA exposes that none of these ongoing activities are
5 occurring.

6 54. The FDA continues to keep TEPRSSC defunct. Thus, to address the four petitions to
7 regulate LED products submitted by the Soft Lights Foundation, the FDA turned to “*an*
8 *independent, third-party organization*” to conduct a literature review. The FDA has
9 chosen to hide the identity of this third-party organization from public scrutiny, and
10 therefore it is not known if this party is independent. It is not known if this third-party
11 organization is qualified to review information on the impacts of LED Visible Light
12 radiation. It is not known if this third-party organization has any conflicts of interest. It is
13 not even known if this third-party organization consists of more than one individual. The
14 decision by the FDA to not use its own 15-member advisory committee, TEPRSSC, and to
15 instead contract with a secret third-party entity to perform a literature review does not meet
16 the criteria for reasoned decision making.

17 55. The FDA relied solely on the submission of evidence submitted by the Soft Lights
18 Foundation, and a review of this submitted evidence by a single unknown person or entity.
19 After this review, the FDA again stopped all involvement with LED products and returned
20 to its non-active state in relation to LED products. The FDA is mandated by 21 U.S.C.
21 360ii to establish a radiation control program for LED products, which is an ongoing
22 program that is continually testing, researching and reviewing LED products and which
23 requires full time staff to carry out this program. There is no indication from the FDA that

1 there is even one full time staff member dedicated to operating a radiation control program
2 for LED products. The FDA's finding that performance standards for LED products are
3 not necessary is conclusory and does not meet the APA requirement of reasoned decision
4 making.

5 56. POINT 11 (Page 3, Line 11): *“That review concluded that the “overall quality of evidence*
6 *in the literature for any health effects [from LED products] was low,” and that any*
7 *suggestions of adverse health impacts were “inconclusive/inconsistent.” Id. at 18-19. FDA*
8 *also observed that Plaintiff’s claims about the hazards of LED products are inconsistent*
9 *with “internationally accepted consensus standards,” and that the evidence Plaintiff cited*
10 *was insufficient to support his contentions. Id. at 17. The agency therefore concluded that*
11 *insufficient evidence exists to ‘show[] that the regulations [Plaintiff] request[s] to control*
12 *the emission of electronic product radiation from the LED products described is necessary*
13 *for the protection of the public health and safety.’”* There are little or no valid
14 internationally accepted consensus standards for LED products. There are no limits on
15 intensity. There are no standards for the levels of blue wavelength light that are safe.
16 There are no standards that ensure spatial uniformity. There are no standards that protect
17 individuals from LED flashing lights. LED products are constantly evolving and becoming
18 more powerful. If the review by the secret outside agency hired by the FDA concluded that
19 the evidence of adverse health impacts on the public is low, then this most likely proves
20 that the secret outside agency was unqualified for the task of reviewing the evidence. Here
21 is a quote from an individual about LED lights submitted to the Soft Lights Foundation,
22 *“LEDs cause me so many neurological symptoms brain fog, anxiety, depression, OCD,*
23 *headaches”*. (APPENDIX A). Here is another quote, *“I can no longer go to the local*

1 *grocery store under any circumstances, its too bright, and the list of places I cant go is*
2 *growing as businesses install this harsh intense LED lighting.” Id.* These reports of harm
3 from exposure to LED lights are being submitted to the FDA monthly, and yet the FDA
4 still concluded that LED products need not be regulated. The FDA’s decision to not
5 regulate LED products is based on the opinion of a single unidentified individual or entity
6 and without transparency. The FDA’s processes do not meet the criteria for reasoned
7 decision making that is required by the APA.

8 57. POINT 12 (Page 4, Line 22): *“Count One Fails to State a Claim that Defendants Violated*
9 *the Radiation Control for Health and Safety Act”*. Plaintiff’s claim under the FIRST
10 CAUSE OF ACTION states, *“The FDA has failed to comply with any of the requirements*
11 *of 21 U.S.C. 360ii(a)(1), (2), (3), (4), (5), or (6) and publish performance standards for*
12 *LED products.”* Collectively, elements 1 through 6 are known as the radiation control
13 program for LED products. As detailed in Plaintiff’s original complaint and in this
14 response, the FDA has failed to implement any of elements 1 through 6 and has therefore
15 failed to establish a radiation control program for LED products, in violation of 21 U.S.C.
16 360ii. The publication of performance standards is just one of the actions required by the
17 FDA as part of a radiation control program for LED products, and thus the FDA’s focus in
18 their response on only the publication of performance standards is an attempt to deflect
19 from the failure of the FDA to test, evaluate, research, share information, and cooperate
20 with other federal agencies on minimizing exposure to, and emissions of, LED light to
21 protect public health and safety.

22 58. POINT 13 (Page 5, Line 3): *“To the extent Count One can be construed as a claim under 5*
23 *U.S.C. § 706(2) of the APA, that claim fails because Plaintiff does not identify any final*

1 *agency action.*” As already stated by both the FDA and Plaintiff, the FDA issued the final
2 agency action on May 24, 2024, and denied all four Soft Lights Foundation petitions to
3 regulate LED products (DEFENDANT EXHIBIT 1). With the final agency action of
4 denying all four petitions, this lawsuit is now the only mechanism available to Plaintiff
5 under the APA to compel the FDA to comply with 21 U.S.C. 360ii and establish a radiation
6 control program to minimize exposure to, and emissions of, Visible Light radiation emitted
7 by LED products.

8 59. POINT 14 (Page 5, Line 15): “*Alternatively, to the extent Count One can instead be*
9 *construed as an effort under 5 U.S.C. § 706(1) to compel FDA to promulgate performance*
10 *standards for LED products, Plaintiff fails to establish that such standards are required by*
11 *statute.*” Again, the FDA attempts to distract the Court from the true nature of the
12 situation. The publication of performance standards is just one element of a radiation
13 control program. Other actions include ongoing research, testing, evaluating, sharing
14 information, and maintaining a liaison with other federal agencies. The FDA is doing none
15 of that. As shown above, the only action the FDA has taken involving LED products is to
16 hire an unnamed outside third party, with unknown qualifications, to perform a literature
17 review. Once that literature review was performed, the FDA stopped being involved with
18 LED products. 21 U.S.C. 360ii(a)(6) requires the FDA to consult with NHTSA, DOE,
19 FAA, FHWA and other federal agencies on techniques, equipment, and programs for
20 testing and evaluating electronic product radiation, and the development of performance
21 standards to control such radiation emissions. These requirements are non-discretionary
22 and thus the FDA’s reference to the Ninth Circuit case *San Luis Unit Food Producers* is
23 not applicable because in that case, the agency had “discretion”. In this case, the

1 establishment of a radiation control program for LED products, the consultations with other
2 federal agencies, the testing, the evaluating, the research, and the development of
3 performance standards for LED vehicle headlights, LED streetlights, and LED flashing
4 lights and the entire class of LED products, is non-discretionary.

5 60. The FDA refers to *Norton vs. S. Wilderness All* as demonstrating that Plaintiff has failed to
6 show that the issuance of performance standards is legally required. An agency may not
7 act arbitrarily and capriciously when making decisions. In this case, the FDA has relied on
8 a single, unknown, unqualified, third-party person to perform a literature review, which
9 claims, without justification, that there are “internationally accepted consensus standards”
10 already in place for regulation of LED products. Even if we were to believe that such
11 consensus standards for LED products exist, this does not absolve the FDA of complying
12 with 21 U.S.C. 360ii(a)(6), which states, “*The Secretary shall establish and carry out an*
13 *electronic product radiation control program designed to protect the public health and*
14 *safety from electronic product radiation. As a part of such program, he shall consult and*
15 *maintain liaison with the Secretary of Commerce, the Secretary of Defense, the Secretary*
16 *of Labor, the Atomic Energy Commission, and other appropriate Federal departments and*
17 *agencies on (A) techniques, equipment, and programs for testing and evaluating electronic*
18 *product radiation, and (B) the development of performance standards pursuant to section*
19 *360kk of this title to control such radiation emissions.” The FDA has failed to establish*
20 *and carry out an electronic product radiation control program for LED products. The FDA*
21 *has failed to consult and maintain liaison with NHTSA, DOE, Access Board, CPSC, EPA*
22 *or any other federal agency on techniques, equipment or programs for testing and*
23 *evaluating Visible Light radiation from LED products. The FDA has failed to collaborate*

1 with NHTSA to publish performance standards for LED vehicle headlights. The FDA has
2 failed to work with the EPA to minimize emissions of unnecessary outdoor LED light. The
3 FDA has failed to liaise with the CPSC to set restrictions on intensity for indicator lights on
4 washing machines and cordless tools. The FDA has failed to engage with the Department
5 of Energy to set limits on the level of blue wavelength light emitted by LED streetlights.
6 The FDA has failed to communicate with the FAA to ensure that pilot vision is not
7 impaired by LED flashing lights on radio towers. The FDA has not spoken to the Access
8 Board about what standards are necessary to ensure that the use of LED products does not
9 create a discriminatory barrier for individuals with disabilities.

10 61. In choosing to not publish performance standards for LED products, the FDA has acted
11 unilaterally, without consulting with other federal agencies. This unilateral action is not
12 permitted under 21 U.S.C. 360ii. Since the FDA is the ONLY federal agency with
13 authority to regulate electromagnetic radiation from LED products, NHTSA is dependent
14 on the FDA for the development of performance standards for LED vehicle headlights.
15 The DOE is dependent on the FDA for development of performance standards for LED
16 streetlights. The Department of Education is dependent on the FDA for the development of
17 performance standards for LED lighting for school classrooms. The EPA is dependent on
18 the FDA for development of performance standards for outdoor lighting. The FDA has
19 violated 21 U.S.C. 360ii(a)(3) and 21 U.S.C. 360ii(a)(6), both of which mandate that the
20 FDA cooperate with other federal agencies. A unilateral decision by FDA to not publish
21 performance standards for any LED product violates the obligations of other federal
22 agencies to protect public health and welfare from LED light. Plaintiff has shown
23 definitively that the FDA is in violation of 21 U.S.C. 360ii and that the FDA is legally

1 required to comply with all six elements of 21 U.S.C. 360ii(a) and establish a radiation
2 control program for LED products.

3 62. POINT 15 (Page 5, Line 22). *“And his allegation that FDA violated of 21 U.S.C. § 360jj by*
4 *failing to submit reports to Congress, Compl. ¶ 73, fails because that section only requires*
5 *reports to be submitted “from time to time” as FDA “may find necessary,” id., and*
6 *Plaintiff does not identify any specific report that FDA was obligated to submit yet did*
7 *not.” “Time to time” is not equivalent to never. Because the FDA never established a*
8 *radiation control program for LED products, the FDA never developed a policy for how*
9 *often it should submit reports on LED products to Congress. Because the FDA dissolved*
10 *TEPRSSC, FDA officials are not receiving any information about LED products. As a*
11 *result, Congress is not being kept informed on the impacts of LED products. Congress*
12 *made completely clear in passing the 1968 Radiation Control for Health and Safety Act*
13 *that the FDA is to be actively engaged in protecting public health and safety from the*
14 *harms of electromagnetic radiation, that the FDA is to be transparent by recording*
15 *TEPRSSC meetings, and that the FDA is to keep Congress informed. The FDA has failed*
16 *to meet any of these obligations established by Congress, Congress is not receiving the*
17 *required reports, and Plaintiff is suffering irreparable harm from the FDA’s failures.*

18 63. POINT 16 (Page 7, Line 11): *“Plaintiff brings his equal protection challenge as both an*
19 *APA claim and a constitutional claim, Compl. ¶¶ 74-78, but both challenges fail because*
20 *Plaintiff fails to plausibly allege a violation of the equal protection clause.” 5 U.S.C.*
21 *706(2)(B) states, “To the extent necessary to decision and when presented, the reviewing*
22 *court shall decide all relevant questions of law, interpret constitutional and statutory*
23 *provisions, and determine the meaning or applicability of the terms of an agency action.*

1 The reviewing court shall hold unlawful and set aside agency action, findings, and
2 conclusions found to be contrary to constitutional right, power, privilege, or immunity.”

3 Plaintiff has a 5th amendment constitutional right to equal protection.

4 64. POINT 17 (Page 7, Line 14): *“To state a claim under the equal protection clause, Plaintiff*
5 *must allege that he is a member of a class that has been “treated disparately” by the*
6 *government as compared to another ‘class that is similarly situated.’”* As clearly stated in
7 the original complaint, Plaintiff is a member of the class of individuals who have a
8 disability. Thus, there are two classes of individuals, those without disabilities who may
9 not experience acute adverse reactions from exposure to LED light, and those individuals
10 with disabilities, including Plaintiff, who experience acute trauma such as non-epileptic and
11 epileptic seizures, migraines, vomiting, panic attacks, and suicidal ideations when exposed
12 to LED light. Each class is similarly situated because they drive on public streets, attend
13 schools, shop at grocery stores, and perform all aspects of daily life similarly. The
14 difference between the two classes is that Plaintiff is a member of the disability class that is
15 unable to neurologically tolerate the Visible Light radiation emitted by many LED
16 products.

17 65. POINT 18 (Page 8, Line 2): *“In addition, Plaintiff must plausibly allege that any disparate*
18 *treatment of these two groups was not justified under the appropriate level of review.”* The
19 FDA claims that no performance standards are needed because it has not been shown that
20 LED products are unsafe. It is this decision by the FDA to ignore the impacts of LED
21 Visible Light radiation on the class of individuals who have a disability and who suffer
22 non-epileptic and epileptic seizures, migraines, panic attacks, and other adverse
23 neurological reactions that is the disparate treatment of the two groups. The FDA has

1 willfully chosen to ignore the acute impacts of LED light on Plaintiff and other members of
2 Plaintiff's group.

3 66. In the FDA's decision to not consult and liaise with the Access Board before denying the
4 Soft Lights Foundation petitions to regulate LED products, and in the FDA's decision to
5 not publish performance standards for LED products, and in the FDA's decision to not
6 establish a radiation control program for LED products, the FDA has disparately treated
7 individuals with disabilities because that class of individuals requires limits on the
8 intensity, spectral power distribution, square wave flicker, flashing characteristics, and non-
9 uniform spatial characteristics of LED light to ensure that this class of individuals does not
10 suffer life-threatening health impacts.

11 67. LED lights are particularly harmful for Plaintiff because of his disability of autism
12 spectrum disorder. The FDA, by failing to establish and operate a radiation control
13 program for LED products, has thus violated Plaintiff's right to equal protection under the
14 5th Amendment. LED lights capture Plaintiff's attention and overwhelm Plaintiff's
15 neurological system, leading to anxiety, fear, non-epileptic seizures, and life-threatening
16 panic attacks. Due to the lack of regulation of LED products, Plaintiff is regularly injured
17 and discriminated against when exposed to LED lights in public spaces, including LED
18 vehicle headlights, LED streetlights, and LED flashing lights on police cars.

19 68. Congress directed the FDA to protect public health and safety from the hazards of
20 electromagnetic radiation from electronic products. This includes LED products. Congress
21 directed the FDA to minimize the exposure to, and emissions of, classes of electronic
22 products that emit electromagnetic radiation such as LED devices. The fact that the FDA
23 has failed to comply with 21 U.S.C. 360ii violates Plaintiff's constitutional right to equal

1 protection. LED lights are not a natural part of the environment. LED products are a
2 human invention, created in a laboratory, and manufactured with machines. Plaintiff has
3 no natural protection for LED light and it is thus the responsibility of the government to
4 ensure that Plaintiff is equally protected from these human-created products.

5 69. POINT 16: *“Counts Two and Three fail at the outset because they do not allege that*
6 *Defendants engaged in any action at all, much less disparate treatment.”* Inaction by the
7 FDA is exactly what Plaintiff’s lawsuit is about. However, what Defendant calls “inaction”
8 is in fact a deliberate action by the FDA to not establish a radiation control program for
9 LED products. The failure of the FDA of not establishing a radiation control program for
10 LED products is what has led to the indiscriminate placement of hazardous LED products
11 nearly everywhere in public life, and which now deny Plaintiff full and equal access to city
12 and business services. In the language of case law related to the Americans with
13 Disabilities Act, this is called “deliberate indifference.” The FDA has fiduciary duties,
14 including a Duty of Care to Others, and by failing to consider the impacts of LED products
15 on Plaintiff and other individuals with disabilities, the FDA has treated Plaintiff differently
16 from other groups who do not suffer acute adverse reactions when exposed to LED light.
17 Thus, the FDA’s “inaction”, “deliberate indifference”, and “deliberate decision to not
18 establish a radiation control program for LED products” has violated Plaintiff’s
19 constitutional right to equal protection under the 5th Amendment.

20 70. To ensure equal protection under the 5th Amendment, the FDA could prohibit the use of all
21 LED products which would protect both non-disabled and disabled groups equally.
22 Another option would be for the FDA to establish performance standards for LED products
23 that would allow their use without causing harm to individuals with disabilities. What the

1 FDA cannot do, is to allow individuals with disabilities to be confined to their homes,
2 suffer seizures, or commit suicide because of their inability to neurologically process the
3 Visible Light radiation emitted by the radically new technology of LED lights.

4 71. POINT 17 (Page 9, Line 15): *“Far from suggesting any unlawful motive, FDA’s articulated*
5 *findings in its denial of Plaintiffs’ citizen petitions demonstrate that the agency engaged in*
6 *a robust scientific review and made a reasoned judgment based on the available evidence.”*

7 In truth, rather than making a robust scientific review and reasoned judgment, the FDA
8 hired a single unnamed person to perform a cursory review of a handful of studies on LED
9 products. In the FDA’s denial of the four Soft Lights Foundation petitions, the FDA did
10 not reference a single study of the impacts of LED light on individuals with autism, nor did
11 the FDA reference any of the Accidental Radiation Occurrence Reports Plaintiff made to
12 the FDA. (EXHIBIT E). The FDA did not engage in a robust scientific review, and the
13 FDA has failed to implement the required radiation control program for LED products to
14 ensure that the FDA is well-versed on the impacts of LED Visible Light radiation. As
15 noted previously, the FDA has dissolved the FDA’s advisory committee TEPRSSC, which
16 Congress explicitly established to provide the type of continual updating of FDA officials
17 with the latest information on LED products that is Congress required. Thus, instead of
18 relying on the vetted and highly qualified 15 members of TEPRSSC, the FDA has chosen
19 to outsource the review of existing literature to an unnamed, unqualified, third-party. Thus,
20 the FDA’s decisions in regard to ensuring equal protection for Plaintiff are arbitrary and
21 capricious and violate Plaintiff’s right to equal protection under the 5th Amendment.

22 **VIII. CONCLUSION**

1 72. Plaintiff has shown that the FDA has failed to implement a radiation control program for
2 LED products, in violation of 21 U.S.C. 360ii. Plaintiff has also shown that LED products
3 are not inherently safe, and that, even if LED products were safe in the 1960s, LED
4 products manufactured since about 2000 are certainly not safe and require performance
5 standards to restrict intensity, spectral power distribution, square wave flicker, flashing
6 characteristics, and spatial distribution to protect public health and safety. Plaintiff has
7 shown that the FDA has failed to collaborate and maintain a liaison with NHTSA, DOE,
8 Access Board, FAA and other federal agencies to develop and publish performance
9 standards for LED vehicle headlights, LED streetlights, LED lightbulbs, LEDs on airplanes
10 and at airports, LED flashing lights, and thousands of other LED products, as required by
11 21 U.S.C. 360ii(a)(6). Plaintiff has shown that the FDA's deliberate decision to not
12 establish a radiation control program for LED products has violated Plaintiff's equal
13 protection rights under the 5th Amendment. Plaintiff has shown that the FDA has not
14 engaged in reasoned decision making as required by the APA.

15 73. A) For the reasons detailed above, Plaintiff requests that the Court deny Defendant's
16 Motion to Dismiss.

17 74. B) Because the FDA has provided no evidence that it has established a radiation control
18 program for LED products and given that the FDA does not dispute that the FDA has not
19 established an electronic radiation control program for LED products, Plaintiff requests
20 Summary Judgment in favor of Plaintiff.

21
22 Dated: August 3, 2024

23 Respectfully Submitted,

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



March 1, 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 Number FDA-2023-P-3828

Dear Mr. Baker:

This is an interim response to the petition dated September 6, 2023, filed by the Food and Drug Administration (FDA) on September 7, 2023. In the petition, you requested 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 that use Light Emitting Diodes that are used on vehicles, 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.”

FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA regulations on citizen’s petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions about this interim response, please contact Patricia Kaufman of our Office of Policy at 301-796-1174.

Sincerely,

Ellen J.
Flannery -S

Digitally signed by Ellen
J. Flannery -S
Date: 2024.03.01
08:39:44 -05'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health

Exhibit B



9450 SW Gemini Drive
PMB 44671
Beaverton, OR 97008

LED Incident Reports April to July, 2024

July, 2024

July 30, 2024 – Federal Way, WA – Other

LEDs cause me so many neurological symptoms brain fog, anxiety, depression, OCD, headaches, ghosting (ex. When looking at led tail lights and looking away I see them but it's a ghost appearance that's green) , lose my place when talking, visual accomdation spasm trigger, disconnect feeling, nausea. It's been a nightmare with LED lights. Some are worse than others.. especially ones using PWM as their brightness control which induces flickering. Car headlights are the WORST. I can see the flicker of most led headlights it's very uncomfortable.

July 24, 2024 – Blandon, PA – Other

I had an LED come downhill at me with high beams on while I was driving. Despite having light blocking glasses on, and being in my car behind my windshield, I still managed to suffer a temporary vision injury. For several minutes following the car passing me, I had a GIANT hallucination of an oval of light, with regular sight in the dead center, in both eyes. It was my first time experiencing this, and after the second minute I had begun to think it may be permanent. The experience was terrifying, I was over an hour from home, and so emotionally distraught on top of the vision impairment that it was difficult to maintain stable driving.

July 17, 2024 – Sacramento, CA – Autism

I was driving on the freeway in the slow lane, when a tow truck in the fast lane ahead of me suddenly turned on LED strobe lights on the top of his truck. It felt like a lighting bolt when through my body. I instantly closed both eyes and felt like I should drive off the bridge.

July 16, 2024 – Albuquerque, NM – Migraine

When I am too close to these white LEDs, I tend to get a large, massive migraine and then I start to lose control of my senses. I become extremely quiet and my friend that I stay with has been noticing that I would act strange and also tend to get a little violent with him. Again, I have NO control of my senses when I am TOO CLOSE to these bright lights! I end up basically not remembering anything and my friend is telling me like, "why were you acting like that??" And I first did NOT know what was causing the problem, until I figured out that when I am REALLY CLOSE to these white LEDs, I tend to start getting that migraine and then lose complete control of my body! I currently am staying with my friend and where he lives, the city is refusing to take matters of these issues that SOME of the residents are experiencing SIMILAR symptoms. My friend who is Autistic will get really painful migraines! And he'll take WAY TOO many painkillers to try and stop his headaches. Before the city of Albuquerque changed their streetlights to white LEDs, my friend and I have had NONE of these issues. After a few months of

these leds being installed in the city, Me and my friend had started to get these strange symptoms and they have only gotten worse! I've personally contacted the state and city's legislature and administration regarding this problem. BUT they don't want to do anything about the problem! My friend has contacted the whole state PLENTY of times explaining that this is extremely dangerous, but again, they do NOT want to do anything about it! I'm hoping that somehow, we can make Albuquerque replace their led white lights to a softer light like, 2200k HID LEDs and also MAYBE some LED VAPOR lights! I hope you can help force Albuquerque to do this!

July 15, 2024 – Albuquerque, NM – Autism

I am Autistic and have a sensitivity issue with BRIGHT LIGHTS. My city has changed their streetlights to LED 3000k and 4000k lights from streets to parking lots. Ever since these lights were installed, I have been getting constant migraines and large headaches multiple times a month. My city is REFUSING to do ANYTHING to bring back ANY form of AMBER streetlights. I've contacted the city AND state A LOT! And they won't do anything. I've even tried contacting the DOT of the state and he won't even be much help. My city continues to IGNORE my concern and also continues to install these WHITE LEDs. I've tried EVERYTHING I could to help my city but they won't do ANYTHING. I hope I can FIND a way to FORCE my city to bring back these AMBER AND VAPOR streetlights back! My city had installed these lights back in 2019 and I've done EVERYTHING I could to try and make the city understand that these lights are TOO BRIGHT, and I CANNOT continue much longer going to bed every night and waking up every day with a LARGE MIGRAINE that causes me to even become DIZZY at times! I hope you can help me fight this issue in my city and FORCE my city to bring back AMBER AND VAPOR streetlights! Thank you for reading this!

July 9, 2024 – Woodland, California – Autism

A fire truck came down the street with LED strobe lights. The strobe lights caused me to suffer psychological trauma which lasts for hours after the incident.

July 9, 2024 – Mangonui, New Zealand – Migraine

While traveling in the passenger seat along the state highway felt sudden thunderclap pain to the left occiput passing three flashing LED lights on three diggers repairing the road. My left eye began to stream, my speech became slurred, then dysaesthesia to the left side of my face and arm occurred. I felt as though I had a concussion. The symptoms of this hemiplegic migraine event resolved gradually over a three day period.

June, 2024

June 29, 2024 – Hillsboro, OR – Other

My partner and I are blinded by LED headlights that drive behind us these days. It is getting worse. WE ABSOLUTELY HATE IT!!! It's unsafe and poses a safety hazard. LED Headlights are basically high beams. At least "high beams" have regulations on when they can be safely used.

June 21, 2024 – USA – Autism

An individual contacted the Soft Lights Foundation to report thoughts of suicide due to repeated exposure to blue-rich LED lights such as vehicle headlights. The neighbors called the police who came out for a welfare check. The police stated that only the city council could do something about the LED lights.

June 14, 2024 – Havre, MT – Other

The Bureau of Reclamation, a federal agency, is conducting a three-to four year construction project near our home. They are using high-intensity LED lights on the site. Our home is over one-half mile away from the site and 100 feet higher in elevation but the construction lights are projecting into our home, lighting it up from end to the other, and have been doing so since the summer of 2023. We have been asking them to modify their lights since August of 2023. When I started having daily migraines in December of 2023, we started blocking some of our windows with cardboard, but the damage turned out to be far worse. A few months ago, my husband was diagnosed with a sudden and drastic change of vision in one eye which alarmed his ophthalmologist, who was unable to find any physical reason for the loss of vision.

June 12, 2024 – San Tan Valley, AZ – Migraine

It literally feels like it is burning my retinas. I no longer feel safe driving at night. It's not safe for me or others. I don't know what to do. I feel like I'm going crazy.

June 12, 2024 – Tampa, FL

I recently visited a local establishment for lunch and every single one of their lights had 5000k (maybe even higher) bulbs in their fixtures. The color wasn't the only problem, but they clearly used some cheap bulbs with a very low CRI and a terrible flicker rate.

I'm normally not *that* sensitive to bad lighting, but this place in particular immediately triggered a full migraine and a feeling I can only describe as nauseating. I looked up pics on Google maps and years ago this place had nice warm lighting and used Edison style incandescents. Makes sense that I had no ill effects the last time I was there.

June 8, 2024 – Brantford, ON, Canada – Photophobia

I am blinded by LED headlights while driving. This is extremely unsafe. LED headlights should be banned.

June 5, 2024 – Escondido, CA

As I walked into my local Costco, I was assaulted by an LED demonstration light. Immediately I got a headache and my vision turned blurry. Even after getting past the light, the effects lingered. As I walked down the first aisle, another demonstration light hit me, with the same result. I spent the rest of my time shopping under duress. I spoke with Jose H., the membership manager, and explained how dangerous those lights are, especially to people with neurological sensitivities, that they can cause seizures and worse, and requested that they be turned off. He said he couldn't do anything. He would have to confer with the corporate office.

June 5, 2024 – Doylestown, PA

The LED lights are like Searing Laser High Intensity Lights that BLIND the drivers visibility and harm my eyes with pain and headaches. There is no avoiding them, I find I have to shield my eyes anytime one of the LED vehicles come toward me on the road. It is Impossible at night to drive and extremely difficult during the day I suggest going back to a softer headlight and putting an AMBER shield on vehicles that have LED lights to soften and stop the blinding that they cause or best go back to the softer traditional lights. It is IMPOSSIBLE to drive at night and will eventually lead to burned out retinas and macular degeneration with this constant blazing brightness directly in the drivers eyes.

June 4, 2024 – Petrolia, CA

At night when an oncoming car or especially truck has LED bright lights, I stop right where I am. I can't see to move forward lest I drive into the oncoming vehicle or drive off the road, hit a tree or down a hillside. This happens frequently in the rural areas. In town, I cannot see pedestrians or even signal lights when the headlights are aimed at me. It makes all the other features like crosswalks and parked vehicles disappear. Certain headlights are a danger and I'm glad I haven't had an accident from being blinded by them.

June 4, 2024 – Cumberland, MD – Migraine

I have spent many hours trying to block the harsh alien light that floods our house since the LED streetlight has been installed in front of our house. It is summer now with leaves on trees. The light will be even more intense and be on for longer times in the winter. When I step onto my porch in the evening I am blinded by the LED streetlight and it is difficult to leave the porch without the risk of tripping on steps. I no longer take evening strolls because of the blinding glare on our streets. When I do walk at night, I get red spots in my vision and suffer headaches. I have had several panic attacks while trying to sleep. I feel that these have been triggered primarily by the oppressive feeling that my home and home life has been severely impacted and there is nothing I can do about it.

June 3, 2024 – Oakland, CA – Other

blinded by oncoming headlights and totaled my car (1-17-2024)

June 1, 2024 – Fairfield, CA – Autism

During the day, I was driving a vehicle on a freeway when I struck by an LED flashing light from a bicycle on a parallel road. I reactively closed my eyes and then suffered a seizure reaction, which I would describe as like an electrical shock and loss of cognitive functioning and vision. I then had to emotionally fight off a panic attack.

May, 2024

May 31, 2024 – Logan, UT

Our city has a 'suggested' policy of dark sky compliance where often they will cheap out violating EISs for various road projects. I successfully had a 'cobra' style HPS light typically used at interstate interchanges removed from near my home due to light pollution. Now on the street the rest are being phased out for Dark Sky Compliant (DSC) LED lights and it is a wonderful change. The light is diffuse, lights up the sidewalks, and has minimal spill onto homes or the street. A new hotel has been built across the street from us and the owner incorporated Dark Sky Compliant LED lights in the parking lot and surrounding and it is only slightly more bright at night than before, and it is safe for the hotel guests. I'd recommend making formal comments to Beaverton City to mandate future construction to be DSC and incentivize retrofits to meet DSC. Glaring lights are only slightly less annoying to me than sound pollution, but I've worked with our city to address both.

May 30, 2024 – Jaffrey, NH –

Being the director of a public library which offers evening hours, I regularly need to drive the 1/2 commute home in the dark. I also help care for my 93 year-old father, which again requires night driving. I am not elderly, do not wear glasses, and just passed the vision portion of my driver's license renewal. I have no health issues that would make night driving difficult.

The new LED headlights have made night driving extremely dangerous for me and by extension, anyone else I encounter on the road. I am literally blinded by the headlight intensity of both the oncoming traffic and the cars behind me if they have LED headlights. I studiously attempt to not look at the oncoming cars with LEDs, which means I don't have full visual scope, but as I live in a rural area, cars can come from around corners or over hills before I know where exactly to focus my eyes to avoid direct contact; thus I am constantly dazzled. If I accidentally have even a momentary direct eyeline contact with LED headlights, I have a blinding afterimage that lasts for several hundred yards. There are no shoulders on the rural highways I travel, so I cannot pull over until my blindness passes (and I would have difficulty seeing the shoulder after exposure anyway). If a car behind me has LED headlights, the glare in my rearview and side mirrors can interfere so badly with my ability to see that I sometimes have to turn all the mirrors away so that the glare is targeted elsewhere—very dangerous, if not illegal. The LED light from the car behind me is so intense, I could easily read a book if stationary. I have begun wearing special yellow glare-reducing glasses to drive at night, but as they reduce and darken my overall vision, this is risky.

I cannot cease driving at night if I wish to remain employed. I cannot cease driving at night if my father is to continue to receive my care. I don't wish to cease driving at night and limit my ability to freely live my life simply because all new cars have ridiculously blinding headlights. The invention of LED headlights has created a real problem in my life, and the danger of an accident is real. There doesn't even seem to be a justification for their widespread use, which is additionally maddening.

I have limited my comments to the issue of safety re LED headlights. In other areas, I also find LED light has reduced my quality of life (I can no longer see the night sky due to neighbor outdoor LEDs, etc.) and am outraged that I am given no choice in the matter of home lighting. For decades, I have line dried all my laundry in an effort to energy-offset my continued use of incandescent lightbulbs. Now it is illegal to sell incandescent lightbulbs and I am consigned to having to spend every night hour of the rest of my life illuminated by light that feels like nails on a chalkboard to me. That rant can wait for another day.

Please take complaints regarding LED headlights seriously. They are TOO BRIGHT. How many accidents will need to happen before this is addressed? I know I feel like an accident waiting to happen unless I cease driving altogether, which is not an option and shouldn't have to be.

Thank you.

5/30/2024 – Brighton, England – Migraine

My life has been devastated by LED lights. I am severely triggered by LED lighting, especially car headlights. I experience extreme migraine for up to 2-3 days after looking at a car headlight or a LED strip light, depending on duration of exposure. LED panels in shops, buildings and street lights make me very ill also.

I can be vomiting for 6 hrs or more after exposure and have severe head pain, weakness and complete disability. Consequently I am now pretty much housebound and excluded from all social activities, travel and work. I have tried all the blue light blocking glasses but it is the FLICKER that is the trigger. In the same way strobe lighting affects people with epilepsy.

It is totally unacceptable that so many peoples lives have now been pretty much ruined by ubiquitous LED lighting.

5/28/2024 – Kuala Lumpur, Malaysia – Photophobia
Instant trigger of chronic migraines. Can't even function at all.

5/28/2024 – West Springfield, MA – Other

Driving home at night from visiting my daughter and grandkids, my partner and I who are in our late sixties were constantly bombarded by LED lights. He was behind the wheel while we both kept aware for the usual zig-zagging speeders and with warm weather, motorcycles (why aren't they required to have a red light or reflector on the back of their helmets?).

It's like running the gauntlet having white/ blue blasts of light dazzle you from opposing traffic. Even on highways with wide median strips you never know when you will be temporarily blinded!

There is construction everywhere, lane shifts, narrow temporary lanes with rough pavement and confusing signs and then those lights, sometimes from packs of cars all with LEDs hitting your eyes.

Trucks or SUVs behind you and your rear and sideview mirrors are useless! You have to fiddle around, while driving to tilt the side mirrors or literally drive with a hand up blocking your rear view. This affects all ages but is particularly bad for seniors! Older eyes have slower dilation response to glare. In a way it's age discrimination as older people will have to think twice about whether they can go out at night!

We have laws prohibiting people from shining laser lights into the sky as it can blind pilots in airplanes. This is the same thing. We worry about folks distracted by their phones or impaired by alcohol, but no one thought about super bright lights glaring in your eyes!

This impacts my life. It's dangerous! They should be recalled immediately. Like other car malfunctions manufacturers should change out the lights or put a filter on them. Let's do this now, not in 10 years or so. Switch back to halogen for the safety of all drivers.

5/28/2024 – Winsted, CT – Other

Dangerous driving conditions at night on my way home from work!! I have to literally close my eyes as ridiculously bright LED headlights blind me while passing in the other lane. This is so dangerous and damaging!!!!!!!!!!!!!! How can this not be being addressed. I have almost crashed multiple times. I feel my eye sight is being damaged from these lights and getting worse. Please help up.

5/28/2024 – Bangor, Northern Ireland –

I see that because the Prime Minister has declared there will be an election in the UK, the petition for the issue to be debated has been declared null & void..... Raging ! The reflector size of dipped headlights gets ever smaller, increasing the intensity of dipped headlights – a triumph of style over function !

5/27/2024 – Avondale, PA

Unable to see the road, cars, or surrounding areas while driving when high beam LEDs are in use. Lowering these LEDs to regular or low beam does no use. Even in low setting these LEDs are 10 times brighter than my vehicle's regular incandescent lights and my eyes cannot adjust to account for dark adaptation to drive at night. Ban LEDs in vehicles or reduce them 75% to match other older model vehicles. Also – point them downwards so they light the roads instead of tree tops and telephone poles.

5/25/2024 – Portage, MI – Photophobia

Debilitating headaches, dizziness and seizure like response when exposed to LED lighting. Increased sensitivity to any lighting type after prolonged exposure in LEDs.

5/18/2024 – Houston, TX – Photophobia

While visiting a friend I was exposed to LED from overhead light fixtures in the apartment, and the extreme LED of Samsung TV. Together, they suddenly triggered photophobia, migraine, & brain fog in me and I am not a TV watcher. Just walking into a room with LED TV and lightning or shopping in grocery and drugstores with All the LED now triggers my eyes with pain. Shopping mall is out of the question for me. I have to wear very dark sunglasses and a cap with a bill. I Must have phone and other devices Very dark, And have limited screen time. I have to cover lamp shades with scarves. I've tried blue block glasses which don't help at all. Obviously the LED has caused me to be much less social. It has also caused my eyes to twitch, and has made them have intermittent blurry vision.

5/18/2024 – Los Angeles, CA

LED lights make it dangerous to drive at night because my vision gets blocked while I'm driving a vehicle.

5/14/2024 – Sammamish, WA – Autism

I have largely avoided walking around my neighborhood at night for quite a while because of extremely bright LED headlights, except for viewing the aurora borealis on May 10, 2024, and I was horrified at the growing rate my neighbors are installing very bright LED light bulbs that far exceed 2700 Kelvin. I had to walk to darker parts of the neighborhood to avoid my view being ruined by the glare of LED lights. Even while walking around at 3 in the morning to view the aurora without seeing a single car with LED headlights, I was subjected to extremely intense blue-rich white light LED radiation from many homes along my usual route. I was honestly hoping the solar storm would knock our power out, which didn't happen.

In addition, I witnessed many poorly shielded LED lights without any diffuser at many stations along the newly opened Line 2 Link Light Rail in the Seattle area and was horrified at how these LED lamps are a potential discriminatory barrier. We always talk about diversity and inclusion here in the Seattle area and making transit accessible and yet never consider the needs of those with autism or epilepsy. I've even noticed that many buses by King County Metro (and likely Sound Transit) are now being fitted with LED headlights.

Banning incandescent bulbs is a crime against humanity and an attack on nature itself. We need very strict national light pollution laws instead of doing this at the local level. Or better yet, unban incandescent bulbs and let the customer choose instead of the government doing it for us.

5/14/2024 – Cambridge, NY – Epilepsy

My daughter and I walked out to run an errand one afternoon. As we came around a building, there was an LED streetlamp, still on though it was daytime. I'd been completely fine a moment before, but the light struck me and I was instantly incapacitated by severe neurological symptoms, stumbling and shaking. I couldn't walk, speak or see properly and my face and left arm went numb. We turned back immediately, and my daughter had to hold me upright so we could get away from the light as quickly as possible. We did not complete the errand. About a week later it happened again. This time i was alone, and my impression was that the street lamp snapped on as I got closer. This time there was no-one to catch me. I fell and couldn't get back up again. I was nauseous, dizzy and disoriented, unable to see, my limbs uncontrollably hitting the ground. Eventually I crawled/dragged myself back home and remained ill for many hours. I felt humiliated on top of everything else. I do not know if anybody witnessed what happened. Nobody came to help me and I could not call for help because I couldn't speak.

5/14/2024 – Chicago, IL – Other

blinding me and seeing spots all day. extremely stressed when i have to drive!!!! I hate these lights and cannot believe this is legal!!!!people don't give a crap!!!

5/12/2024 – Hancock, WI

I almost hit a pedestrian on the side of the street because the car in oncoming traffic had blinding LEDs. I did not see the pedestrian until the oncoming car had passed. If the timing was just a little different, there would have been a terrible ending. I reported it to the nhtsa. They said the lights just seem brighter. (This was a few years back.) I used to love driving at night. Now I can't handle the LEDs. This puts more traffic on the road during the day. Even when someone driving next to me has LEDs, I have to lift my hand to cover my side mirror from letting it blind me.

5/10/2024 – Yonkers, NY – Migraine

Led lights blind me in the road and flare up migraine. Have to stay home at night. Interfere with my life. Very dangerous.

5/9/2024 – Saint Paul, MN – Photophobia

My eyes have retinal injury and bright LED lights cause intense pain and discomfort. Overly bright LED's impact my life in numerous ways. There is widespread illegal use of intense LED floodlights in my neighborhood, but the local law for legal use of LED floodlights is not enforced. LED streetlights seem designed to blind drivers, rather than illuminate streets. Streets are dimly lit, but streetlights are shine right into drivers eyes. Vehicles keep their headlights on day and night, and shine into sideview and rearview mirrors. This causes eye pain and discomfort.

5/6/2024 – Cleveland, OH – Autism

LED lights give off a poor quality light, pure and simple. With the cheapening of everything these days, proper fixtures are usually non-existent, i.e., there is rarely any diffusion in the form of a large shade or lens—just the raw diode. For those who have in-focus vision (as everyone strives for with corrective lenses and such), the intensity of viewing a high-powered and undiffused LED at any distance is always an unpleasant one. As it happens literally thousands of times a day, our retinas get “etched” and degraded. This is not to say that an incandescent bulb can't be painful, it's just that in the days of incandescent bulbs we made proper fixtures.

For me, when I'm presented with an unexpected bright source of light, my eye naturally moves and centers it in my vision. There is something physiologically that makes it hard to look away instantly. It literally takes like a complete second to pull your eye away from it. However, the damage is already done. You stared directly into something that was of an infinitely higher magnitude of brightness in relation to its surroundings. THE EYE IS NOT BUILT FOR THIS. These encounters cause a tense visceral reaction throughout the body. Considering that there are BRIGHT LED lights on just about every conceivable object these days, and it's common for someone to have these negative encounters thousands of times in one day, and considering that the center of your vision is by far the most important throughout our lives, the collective pain and suffering is unimaginable.

There's a certain obsession with safety that I believe our society has falsely bought into. For example, daytime running lights used to be a small halogen bulb, perhaps 10 watts. Now, there are cars with many layered stacks of raw LEDs with candela measurements far exceeding our proper range of vision. It is saying that that person's car is the most important thing you ought to see down the road. Animals,

pedestrians, everything else, doesn't get to grab your attention. Your vision system is so overloaded with the fact that "there's that car," that other possible visuals are much harder to see. Overall, the eye does not need that much light to see as long as the relative values are thoughtfully presented (as they used to be).

Nighttime is all but a faint memory as it is almost always ruined by the presence of stinging, streaking, damaging, high candella artificial lighting. We, as a species (and all species living in our vicinity) have lost a cherished and peaceful time; the hours of darkness that we once called, and still hypocritically call nighttime.

I don't believe that our nation should have any real discussion about mental health until we face the reality that we're degrading each other's eyes, our most important sense, on a grand scale.

People are literally suffering and slowly dying from the continued assault on their eyes, and thus, their brains.

5/3/2024 – Amherst, NY – Photophobia

Discomfort, people and sleeping patterns, also disruptive for me from exercising early mornings or evenings with street lights over 2700k

5/1/2024 – San Leandro, CA – Astigmatism

I regularly walk home from work in the evenings, which in the colder months means walking down a dimly lit street. Having poor eyesight and balance, I'm always afraid that the blinding headlights of the cars zooming down the street will cause me to stumble off the sidewalk and into the path of an oncoming car. It certainly doesn't help that some cars have headlights bright enough to leave afterimages in my vision, the last thing I'd want to deal with when walking at night.

April, 2024

4/30/2024 – Roseville, CA – Autism

I was standing in a room and another person's cell phone buzzed with a message notification. The iPhone also pulsed its LED camera flash, which struck me in the eyes. I fell to my knees, breathing hard, and trying to fight off a panic attack.

4/30/2024 – Auckland, New Zealand – Migraine

LEDs cause me to suffer hemiplegic migraines of three day duration. This has resulted in partial confinement to my home, exclusion from municipal life, partial loss of employment and deterioration of health. The migraine results in blurred vision, dysaesthesia to the left side of my face and left arm with severe occipital pain. It has resulted in loss of consciousness on multiple occasions, one of which leading to a three part fracture to my right arm.

4/30/2024 – Swanage, England – Other

LEDs have been fitted as replacements for low pressure sodium street lights in the area where I live, which is within the Dorset Area of Outstanding Natural Beauty and immediately adjacent to a National Nature Reserve. The CCT rating of the LEDs that have been installed here is 4000K, which results in an eerie blue-white light which I find most unpleasant. The glare from the new lights is excessive, to the extent that when I walk beneath them I have to look down at the pavement rather than looking forwards along the road, to keep the lights out of my field of view. The light spill from these lights is

excessive, resulting in the blue-white glare of the lights penetrating the windows of my house, which makes the interior of my home feel unwelcoming. I find that the light penetrating my home negatively affects my sleep quality, even though I have blackout blinds on my windows (the light still penetrates around the sides). This light intrusion was never a problem when the lights were low pressure sodium, as the orange glow was quite restful and not at all disturbing.

My view across the Nature Reserve at night is now compromised by the new LED street lights, which produce an incredible amount of sky glow. My home is just 400 metres from the coast, so there is often mist or fog in this area, and these LED street lights cause the whole area to light up as the light scatters in the mist. It is exceedingly unpleasant. One of the lights is 185 metres away from my house and is over ten metres below it, yet the street light casts a bright image of my window onto my bedroom wall. It is so bright it appears as if a car is parked on the hillside with its full-beam headlights directed straight at my house.

I have been so disturbed by these lights over the past two years that I believe my current condition of ophthalmic shingles (herpes zoster ophthalmicus) was triggered by them. I have been suffering photophobia, nerve pain, a facial rash with blistering and acute inflammation of one eye because of this condition, which has resulted in the hopefully temporary loss of useful sight in that eye. Since I am otherwise fit and healthy and have had no other stress to cause this condition to appear, I firmly believe that it is a direct consequence of the installation of LED lighting outside my home.

4/29/2024 – Irvine, CA – Photophobia

I have photophobia and photosensitivity due to multiple autoimmune conditions, and my life has changed significantly for the worse with the introduction of intense blue-white LED car headlights and the (ongoing) replacement of a large (about 16000) number of HPS lamps with LED fixtures (at correlated color temperatures of 3000 K and 4000 K) in my city (Irvine, CA).

Street lights:

Bright exposed LED street lights of any color, but particularly those above 2700 K, pose a health risk and serious disability barrier for me. Being sharp and pointed sources of high glare and discomfort, they can exacerbate my dry eye symptoms (I have Sjögren's syndrome) and the likelihood of an autoimmune flare-up. As a SLE (lupus) sufferer, I need to keep my daytime exposure to sunlight limited. It used to be that nights were my go-to option for long strolls, a drive to the grocery or restaurant, or a chance to bask in moonlight or stars at night—something that the gentler glow of shielded HPS lamps afforded. Over the past decade or so, and particularly in 2024, most of these basic human comforts have been taken away from me. I have pleaded with city officials to undo the damage and the discriminatory barrier that street lights cause me, and despite their efforts to mitigate a small portion of the damage (I have met with a very modest degree of success) via glare shields in my immediate neighborhood, the city at night is becoming a cheap, vicious display of human sensibilities and human compassion gone awry.

Headlights:

Vehicle headlights with blue-white LED lights piercing into one's eyes from oncoming traffic are the stuff of nightmares—poorly-angled, egregious beam patterns pretending to be “safety features.” Even five minutes' exposure to this type of rampant glare while I drive or sit in a passenger's seat is sufficient to bring on severe eye pain and vision disturbances, headaches that last days, and emotional distress. It is appalling that those objecting to these ill-conceived and risky fixtures are not taken more seriously.

Light pollution is a menace not just to humans but also to wildlife and foliage that suffer without shutters. Researching, designing, and implementing options that are conducive to safety and easy on the eyes must be high on the agenda, an urgent societal cause.

“So benumbed are we nowadays by electric lights that we have become utterly insensitive to the evils of excessive illumination”

— Jun’ichirō Tanizaki, In Praise of Shadows

This evil is eradicable; let’s do what it takes.

4/28/2024 – Algonquin, IL – Photophobia

I can’t go out at night anymore due to the plague that is LED light pollution. It brought me solace. I can’t walk my dog or enjoy it at all anymore. I don’t see wildlife at night anymore. I love nature and it’s harder to appreciate now. I used to love driving but I can’t without immediate extreme dizziness and migraine. I can’t look outside at all when the sun starts to set. The building I work at has hideously bright LEDs that make me ill on a daily basis. I’m always squinting and averting my eyes. ALWAYS. It took many aspects and simple pleasures of my life away and I miss them dearly. Please do something about this! I want my life back!

4/28/2024 – Los Gatos, CA – Astigmatism

With the increase in use of LEDs in car headlights in addition to cars raised too high (or their headlights tilted too high), driving on the roads at night is an incredible hazard. I commonly find myself unable to ascertain details of what’s going on behind me with traffic and the position of other objects/cars when faced with these blinding lights. I have to get creative to even be able to see, and still face blind spots due to these stupidly bright lights. It makes driving dangerous and I can’t believe LED lights in headlights didn’t get banned years ago.

Every day the government allows this is increasing the likelihood of accidents, health issues from staring at these lights and just a generally worse quality of life.

4/28/2024 – Amesbury, MA –

I am blinded by these headlights, streetlights, floodlights morning and night every day. These lights are a hazard on the road and unnecessarily bright and incorrectly dispersed. This is a danger to everyone and regulations need to occur swiftly

4/28/2024 – Ottawa, Canada – Migraine

I am very sensitive to many things, including light and sound. I loved to walk a lot at night when the lights used Halide orange/pink lights. Now that the city has been switching out the Halide lights with super bright LED white street lights my walks are much less enjoyable. It feels like I’m walking around in the day time. I don’t understand this obsession people have with lighting the world up like a giant football stadium. It’s not necessary, it’s not pleasant, it messes with your circadian rhythm. In my case, it can cause headaches and light fatigue. It also hurts our environment. Birds, animals and insects cannot follow their natural rhythms because their environment is so bright at night now. Also, while driving, I’m blinded by headlights that use these horrendous white LEDs. I hope there is an invention of filters for the lights that are currently on vehicles and that it is enforced to add the filters to the headlights. A return to a golden soft colour would be preferable. As well as adding golden/orange filters to street lights and/or a different design that mimics old styles and colours of street lights. I really hope the

government begins to regulate this. It's dangerous for the environment, people's health and eyes as well as creating an ugly world to look upon.

4/28/2024 – Milwaukee, WI –

I am blinded by the brightness of the LED lights not only at night, but during the daytime. Even from a car behind me glaring in mirrors during daylight. Making it dangerous for me to drive. My eyes cannot adjust due to the brightness. I've swerved off the side of the road. Had to pull over. Which is not always possible when there's traffic behind you and traffic coming at you. This is a problem. There should be a limit on the brightness of the LED. This is such an easy thing to fix, but for some reason nothing gets done.

4/28/2024 – Onsted, MI – Astigmatism

I get eye pain and headaches by being exposed to 4500K or higher led lights

Whether I am driving at night or during a sunny day I am constantly shielding my eyes from led low beam headlights, running lights and brake lights. I have to adjust my side and rear view mirrors so I cannot use them to see properly to avoid being dazzled by led lights. If streetlights are on during the day and night I put my sun visors down because the leds are too bright. I drive over 1000 miles a week for my job. I dread cloudy, rainy days, dusk and night driving because of led lights. It's like torture to my senses. I am constantly blinded at night and have been during the day as well because of led headlights. If I am walking in a parking lot on a cloudy day I have to shield my eyes because led running lights are too bright. I have asked my neighbors to shield their outdoor lights or use softer 2700K led and it has caused me civil lawsuits and many legal problems do to this simple request. I have to wear dark sunglasses inside of places that have led lighting. I never had eye pain or headaches prior to led lights. LED headlights are the most dangerous aspect of driving by far. These lights have ruined normal day and nighttime activity for me were they are present.

4/28/2024 – Marshfield, WI – Astigmatism

LED headlights are blinding to the point where I have almost hit deer and other vehicles because I cannot see when the LED lights are coming at me

4/28/2024 – Lancaster, PA – Migraine

I am a migraine sufferer, and my trigger is photosensitivity, especially from intense bright lights. For the last several years auto makers have installed LED headlights and the color temperature they have chosen to use is blinding for oncoming drivers. There truly is no need for the adaptive or "moving part" of the headlight if ya warmer color temperature is programmed into the LED headlight. The extremely intense and blinding colder "blue" white light emitted from LED headlights just feet away is MORE dangerous than looking up at the sun. If focused intense cold bright white light is not dangerous why do welders use masks? It is literally the same reason and effect these OEM LED headlights have on oncoming drivers. How many people need to die before LED headlights are given a warmer light temperature? It is really not that hard. The technology already exists. Just look at the average teenager and how they use LED lights in their bedrooms. They have a small remote and they can change the color and or color temperature of the lights at their will. Thank you for your time.

4/28/2024 – Webster, MA – Other

Large pick up trucks as well as SUVs and other cars especially in MA., were it seems that tailgating is legal, get behind you and blind you from behind making it very difficult to see ahead of you. Same situation with vehicles approaching from the opposite direction.

4/28/2024 – Hamilton, Canada – Migraine

LED headlights on numerous occasions have given such intense sharp pain in my eyes that induced migraines, forcing me to pull to the side of the road and vomit. Glare from LED headlights has blinded me on thousands of occasions. In some of those instances it has taken more than 5 seconds to regain my sight. LED headlights and taillights physically hurt my eyes when I'm in close proximity to them (I.e. stoplight) forcing me to physically block them with my hand. The glare, blindness, eye pain and migraines caused by LED headlights have been confirmed by my optometrist, Dr. Otto Lee. Among eye care professionals, LEDs are a known and documented problem in every age group. Driving at night for longer than 30 minutes has almost always resulted in me getting a migraine, which was never the case before LED headlights existed. As a result, I have to limit my nighttime driving to less than 15 minutes. This limits how much work I can do, or how much I can visit my family, especially in the winter months. I've had to restructure my life around LED lights.

4/28/2024 – Chicago, IL –

Every single day day or night I am blinded over and over again even driving short distances, I get spots and yesterday my eye was in actual physical pain as 1 car was so dam bright like the eclipse!!!! I'm collecting evidence to sue. We all should sue every driver who damages our vision and the government for allowing this!!! you CANNOT drive anymore EVER. Our Country is lost.

4/28/2024- Baltimore, MD –

I can't for the life of me understand how this is even something I have to report.

Do none of these people drive at night or in inclement weather?

Do none of them pass billboards?

I used to love driving at night, even prefer it in some cases, but the new street lights are terrible, especially the defective ones that turn purple and create such harsh lighting I literally can't look at it. And the LOW beams on the new cars are more blinding than some of the old high beams!!!! I've flashed my lights at other drivers to alert them they're driving with high beams on and they flash back that it's their low beams.

Not only does it "daze" my eyes so that I see spots and can't see the road properly for a few seconds, but it also creates harsh lighting conditions that makes it hard to discern what's hiding in the shadows behind objects like trees and street signs.

And the blue hue of these LEDs that's being used is also not only harmful and exhausting on the eyes but colors things weirdly so it's harder to tell what's what.

The car I drive still has "older" (aka not blue or insanely bright) headlights, and I used to love renting cars for longer trips but now every car I rent has those headlights which makes it an unsafe environment to drive in, and in those vehicles I have other cars flashing their lights at me to alert me I'm driving with high beams when I'm not!!!! Which again, causes a "daze" and I see spots and my sight is not clear while I'm maneuvering roads at night.

This is clearly unsafe!!!

I'm in my 30s! I don't have other eye problems and I shouldn't sound like a crotchety old person when talking about driving at night! It's absurd!

In addition to all that, I've recently experienced billboards that switched from canvas to LED and LED signs outside of businesses that are so insanely bright you can probably see them from space. It might be necessary during the day when the ambient light is brighter, but these things need light sensors and to adjust to a dimmer display during the night time. Because when I drive by it's like someone shining a

flashlight in my eyes for a minute. It's absolutely not safe!!!!

I have a similar issue with the road crews that do construction on the highway at night. A bunch of those crews have these flood lights that are supposed to illuminate the area for them but they aim them in such a way that they blind the drivers too! Who's "genius" idea was that!?

Either the people making these things are blind as bats anyway or they just don't care.

4/28/2024 – Fareham, United Kingdom –

Comment on statement "DOE researched studies and other publications to ascertain any known impacts of LED lamps on human health and has not found any evidence concluding that LED lighting used for general lighting applications directly results in adverse health effects.": 'General lighting applications' is not the same as directed beam applications & the FDA should recognise this situation in the case of headlights.

4/27/2024 – Rodeo, CA –

I drive a fairly small car. On the highway at night, I find the excessively bright LED headlamps are both disrupting and an impediment to driver safety. As cars approach from the rear on either side, their headlamps reflected in my side-view mirrors are often so dazzling that I have to hold my hand in front of the mirror to be able to safely see the road. Even with my rear-view mirror in the "night" position, the brilliance of these headlamps when behind me can be distracting and blinding.

When approaching from the opposite direction, especially on narrow roads, they present even greater threat to driver comfort and safety, often causing momentary blindness. The worst cases are often Tesla headlamps, but many newer SUVs and pickup truck headlamps exhibit similar characteristics and are very nearly as bad.

These headlamps are unnecessarily bright, producing a spectrum of light that is especially blinding. They often illuminate not only the road, but the overhead road signs and the interior of the cars ahead of them. These headlamps are both a nuisance and a hazard to other drivers. And, in recent years, it seems to be getting worse. The headlamp arms-race is rapidly getting out of control at the expense of driver safety. Car makers must be made to comply with existing headlamp regulations, and, in fact, those regulations must be amended to consider ever increasing lux levels, higher color temperatures, and broader and taller light-pattern spread.

4/27/2024 – Tuscon, AZ –

LED headlights are having a negative impact on my driving continuously. I have good night vision, excellent reflexes, am generally quite alert at night. But I rarely drive at night because of the hazard of LED headlights. They blind me to the point where I cannot see the road AT ALL. I have very mild cataracts, and LED headlights totally make me see nothing but white. The only way I can navigate safely is to MEMORIZE the road ahead while I can still see it, and DRIVE TO THE RIGHT of the oncoming car. If it is a road I am not familiar with, I might not be willing to drive it at all. It is too easy to be surprised by an unexpected curve when I cannot see the road. I drive prudently. I am not willing to put up with this hazard. So I do not drive at night if I can possibly help it, and this has an impact on my life, and my ability to get home safely if I end up having to stay someplace away from home longer than anticipated. People are going to do what they have to do to stay safe. The mere fact there are not more accidents is not proof that LED headlights are safe. It is only proof that people try to avoid hazards, and may not be driving at all during nighttime hours. And what kind of harm does a laser directly into the face do to the eyes any time of day? Unanswered question.

4/27/2024 – Izhevsk, Russia – Other

I cannot stand the LED headlights. It all started about 4 years ago when the amount of cars with LED headlights started to become noticeable. I understood at that time that I couldn't look at these lights because my mind goes sick, my eyes begin immediately to get irritated to a very considerable degree that it really hurts, my muscles are becoming stiff and I get nervous tics, that is involuntary rapid head movements. Moreover, I begin to feel some sort of panic attack. Back then the amount of cars with LED headlights in my area was around 12-16 percent and it was possible to get along. Since then, the situation only got worse. The amount of cars with very blinding and extremely piercing LED headlights nears probably already 40 percent in my area and I gave up at all staring in the oncoming traffic direction because I just cannot do it any more.

Because of a neurological condition, I was not allowed to drive a car and now it seems that it's even for the better. I cannot even imagine how people drive nowadays with this killer light. In my country we have day running headlights as a must so the headlights are on 24/7. While there is a sunny and clear weather I can somewhat go along the road facing the opposite direction, but with a gloomy weather, rainy weather, dusk, let alone nighttime I cannot physically do this. I have to avoid major roads going either along residential areas with much less traffic or going along a pavement that runs parallel to the incoming traffic, thus I somehow can move away my head and eyes and to see what is going on on the upcoming lane (a lane that is further away from the pavement). When using public transport I have to sit in that part of a bus/tram that has windows on the left right from the driver seat. so that I am spared to see the upcoming lanes with the upcoming traffic.

Thanks to all this, to a huge light pollution caused by LEDs and other numerous LED lights sources sprung up recently, I am almost confined at home during nighttime because I cannot stand this light. Only warm shielded LED in moderate quantities are more or less OK for me, but unshielded LEDs over 3000 K, bright LED shop signage, LED digital billboards and LED decorative building lighting makes me have fits of very severe panic attacks. I don't feel these attacks at all with outdoor halogen headlights and sodium/incandescent/CFL lamps or warm (2700 K and less LEDs in moderate quantities). The indoor LED lighting has less negative impact on me, though too much white indoor LED light is also uncomfortable while the indoor white fluorescent light is quite OK for me.

I am asking the US regulatory agencies to give the answer why LED light can trigger severe panic attacks while other light sources are quite alright and even uncomfortable. I am sure that I am not alone.

4/27/2024 – Elk Grove, CA – Autism

The Ziosk portable kiosk payment system has a bright LED screen. During dinner at a Chilis restaurant, we placed the kiosk face down on the table to avoid exposure to the LED Visible Light radiation from the LED screen. At payment time, my partner inserted the credit card for processing. At the completion of the processing, a large white LED light on the side of the kiosk suddenly irradiated me with white LED Visible Light radiation.

Due to the intensity of the white light, everything around me became black, except for the overwhelming feeling of bright white light. I felt disconnected from reality and as if I had entered a nightmare dream. I believe that I was partially unconscious. As I began to recover consciousness, I thought that perhaps I was staring at the LED flash on a cell phone, but that this was much more powerful. Then, as I became more aware of my surroundings, I realized that that the white light was from a large, white LED from the side of the Ziosk device.

I felt nauseous, so I fell to my stomach and tried to vomit, but I only ended up coughing. I then felt overwhelming anxiety and panic and went to the kitchen, demanding accommodation. A staff person then began yelling at me. I ran outside screaming. I continued to try to vomit, but only spit came out. At some point, both of my hands went numb and tingly.

The police were called. I dialed 911 to tell them not to turn on their LED flashing lights, but they had the red and blue flashing lights on, which further debilitated me.

4/27/2024 – Coudersport, PA –

I am beyond infuriated with the use of bright white LED lights, I'm beyond frustrated with the searing eye pain that LED lights procure, I am beyond infuriated with the intense migraines that I suffer from when dealing with bright white LED lights. I am beyond frustrated with the amount of pain that is brought upon me due to these LED lights. They are an unnecessary monstrosity that never should have been brought into public view! They are NOT beneficial in any way, shape, or form. In fact they are detrimental to society and the environment.

4/25/2024 – Horseheads, NY – Astigmatism

I have astigmatism, which is 30% of the population of ALL ages. LED headlights and all bright white LED lights give me a wicked headache all day that pain meds don't touch. I rented a car recently with LED headlights & I had a huge headache from the headlights reflecting off of other surfaces. So I can't even drive a car with LED headlights. Just in the past couple of weeks, I almost was in 3 accidents while being blinded by LED headlights. I have no problem with halogen headlights. My work commute is on a 2-lane road for an hour & I need to work to live. I can't just stay home. What kind of life is that? So I have to put my hand up to block the headlights of the line of cars going the opposite way and look at the white line. One morning when it was raining thus more reflections, I was on a slight bend and looked up just in time to see an older SUV unsafely trying to pass a huge line of cars coming right at me in my lane. They were hurrying to get back over maybe 20 feet from the nose of my car. They had aftermarket LED headlights, so it was like two big floodlights that blinded me. The 2nd time was I was approaching a roundabout and pickup truck from the opposite side had blinding LED headlights. I checked to make sure no one was coming from the left before I got there, but *poof* a car appeared out of no where and honked at me. They almost hit me. I was so distracted by being blinded by the LED headlights, I didn't see them. And another time I was at a crosswalk and had been stopped for other pedestrians. But a car going the opposite direction had blinding LED headlights. I didn't see the additional pedestrians until I was passing over the crosswalk. I had looked too. The pedestrian had thankfully stopped. They were partially blocked by my windshield frame too. Again, I never had these problems with halogens. LED headlights are dangerous! Explain to me how lights that are 800x brighter than halogens are not blinding other people. LED headlights are marginalizing almost 50% of the population...specifically people with disabilities that include astigmatism (30%), migraines (17% women & 6%), and seizures (4%). And we can't forget age discrimination against seniors with cataracts. It also affects the circadian rhythm and eye health of both people and wildlife...all of them. That is why there are blue light filters on devices. Please do the right thing and ban bright white LED headlights and LED lights in general.

4/24/2024 – Mantua, NJ

Multiple incidents. I had to cancel 2 gym memberships because of bright LED lighting they installed, and there's no gym within a workable distance that doesn't have this insane lighting. I've cobbled together used gym equipment at home for more money than I could afford.

I can't work without special tinted glasses, or I get migraine symptoms within minutes. Even with this

protection there are places I cant stand and directions I cant look because some of the LED fixtures are simply too intense and instantly painful.

I can no longer go to the local grocery store under any circumstances, its too bright, and the list of places I cant go is growing as businesses install this harsh intense LED lighting.

Shop Rite, Five Below, Giant Fitness, Planet Fitness, Pantry One, T Mobile- these are some of the places I simply cant enter with any level of protection short of a complete blackout blindfold.

4/23/2024 – Dallas, TX –

Makes me blind and hard to see road. Especially oncoming traffic when the lights are elevated higher than me.

4/23/2024 – Sammamish, WA – Autism

I'm a lifelong resident of the Seattle area, and I was diagnosed with Asperger syndrome in early childhood. Additionally, I have been diagnosed with depression, adjustment disorder, anxiety, attention deficit disorder (ADD), and I suspect that I might also have undiagnosed post-traumatic stress disorder (PTSD).

My biggest concern, especially in the last couple of years, is the dangerously bright light-emitting diode (LED) headlights that have been proliferating on our roadways at a disturbing rate since the early 2020s. They have had deleterious impacts on my quality of life since I can no longer exercise outdoors or drive at night without fear of being exposed to excessively bright LED headlights, experiencing sensory overload, and having meltdowns as a result. Even during sunny days, if drivers leave those LED headlights on, they are still too bright and extremely unpleasant to look at; it's particularly worse when it's cloudy or raining. LED headlights, especially those on Teslas, are some of the worst offenders, to the extent that I can recognize a Tesla from a distance solely by its headlights.

I am an avid lifelong cyclist and ride my bike all over King County. I have visited places such as Skagit County, Whatcom County, Snohomish County, Pierce County, Vancouver Island, Point Roberts, Snoqualmie Pass, Cle Elum, Vashon Island, Whidbey Island, the Kitsap Peninsula, and San Juan Island— all by bicycle. I have also ridden on nearly every regional trail in the Seattle area as well. However, my enjoyment of this activity has been greatly diminished by the excessive glare from these LED headlights, starting in the early 2020s. I have effectively lost one of the best stress relief methods I use to cope with my mental health issues, compounding my problems even more.

I also enjoy going on walks, and they have also been impacted by these LED headlights, making it unpleasant for me. I can no longer enjoy walking outside at night, robbing me of the ability to walk during times when it's cooling off during what are supposed to be pleasant summer evenings. Again, even during the day, I constantly encounter excessive LED radiation and glare from these LED headlights.

Earlier this winter, my neighbor was driving a rental car equipped with LED headlights, which shone into my bedroom when they returned from work in the evening. They have since returned to their regular car, which still has halogen bulbs; however, one of their halogen lights has burned out, and I'm afraid the owner might install LED headlights to replace it. Despite this, I still have LED headlights shining towards my bedroom from passing drivers since I live near a "T" intersection. This situation makes me feel unsafe in my own home, particularly during winter when daylight is limited.

The distress caused by these lights has led to hospitalization, and I feel as though I'm under house arrest because of them, causing serious mobility issues for me. I have written to ALL, and I mean ALL, of my elected officials at the state and federal level, and the lack of any adequate response has only added to my frustration and anguish.

My ultimate goal is to urge the government and policymakers to acknowledge the problems of these excessively bright LED headlights and the dangers they pose to the general public. I advocate for regulations on their brightness and for using a warmer color temperature instead of the bluish light, which disrupts circadian rhythms and makes it difficult to spot road hazards at night.

Personally, I wish to see LED headlights banned completely from our roadways in favor of tungsten filament halogen bulbs, which are less harsh and easier on the eyes. The so-called benefits of LED headlights are outweighed by the risks they pose to the general public, and for many of the reasons I have cited, they need to be completely banned from our public roadways.

I'm extremely appalled and deeply troubled by the fact that I cannot safely use public rights of way that I have paid my tax dollars for because these LED headlights have formed a discriminatory barrier and infringe on my constitutional rights to freedom of movement. I strongly urge the Food and Drug Administration to take action. I believe that these lights are a threat to national security and public health, and swift action must be taken. The current situation is completely unacceptable!

4/22/2024 – Wakefield, MI –

Sitting in the left-turn lane waiting for the light to turn green, the pickup truck in the opposing left-turn lane had a new pinpoint LED turn signal that was so bright and so focused, was like a laser pointer shooting right into my right eye. Even in broad daylight the LED was so bright and so focused like a laser pointer I had to shield my eyes with my hand until the traffic light turned green and I completed my turn. Hours later I am still seeing spots with my right eye. Praying there is no permanent damage.

4/21/2024 – Davis, CA – Migraine

I used to go for long walks at night in my neighborhood for exercise and as therapy for my chronic eye migraine issue. Since 2016 when the City replaced all the sodium vapor street lights with LEDs, I have not been able to walk at night due to the harsh glare and brightness of the lights. They are nothing like the old lights. Add to that all the LED house lights that have been installed since then. My neighborhood has become a no go zone. I paid mello roos taxes for years to pay for all the green spaces I can no longer use because of these lights. Some are even on all day and hurt my eyes even in the day time. My health has suffered from not being able to get my walks – weight gain, high blood pressure. And this is just a fraction of the story. I can no longer drive at night because of the intense LED car headlights in my face. I cannot go into town at night to a restaurant or store for the same reason – LED lights everywhere. I cannot travel on a train or bus for the same reason. Airports also have these lights taking the joy out of plane travel. I have to shop for my groceries online in stores like Safeway that have installed these lights nationwide. If I get exposed to these lights, I will get a ripping eye ache that lasts for weeks, a feeling that the surface of my eyeballs has been lased.

4/21/2024 – Beaverton, OR – Autism

LED flashing lights cause me to suffer severe anxiety, panic attacks, and fear.

Exhibit C

30/03/2024

Dr Janine Manuel

Email: janine.m.manuel@gmail.com Phone/ New Zealand: 0064 22 6307308

To whom it may concern :

Mark Baker is a fellow colleague with whom I have worked and collaborated in my capacity as a medical doctor in the field of clinical analysis over the last two years. I also work as a freelance medical translator for a biotech company in Germany. During this period, I have supported two organizations centered on the impact of LED illumination on health, one in the United Kingdom (LightAware) and the other The Softlights Foundation in the United States of America.

As a clinical analyst the information and data I have been party to has shown LED illumination to have neurological consequences (seizure, migraine, headache, and other neurological effects). This includes adverse effects on those with autism.

The effects of LEDs causing seizure, migraine and other neurological conditions have resulted in individuals being excluded from municipal life, loss of employment, confined in part to their home and significant deterioration of their health (previous well and fully participating in life).

In the case of Mark Baker, I attest to the adverse effect that LED illumination has had on his life causing hospitalization, loss of employment (as head of department as a mathematics teacher) and psychological trauma. He is placed on the autistic spectrum. Flashing LED illumination is of particular distress to Mark evoking a fight/flight response, intense sensation of fear and ongoing psychological trauma.

Sincerely

Dr Janine Manuel

BHB MBChB FRNZCGP

Clinical Analyst/ Medical Translator



Exhibit D

June, 2024

To Whom It May Concern:

Dr. John Lincoln of the charity Light Aware introduced me to Mark Baker several years ago. Mark and I have since become friends. One time in spring, 2021, I was talking to Mark on the phone. I was home in Upstate New York and he was sitting in his car in a park in Medford, Oregon. I'd been telling him about a project I was starting, when he suddenly made a sharp gasping sound, as if he'd just been shocked or struck. Alarmed, I said his name, and asked was he all right? what had happened? but he didn't answer. I could hear a commotion, an agitation like someone moving around or thrashing about, plus a background noise I couldn't identify. I kept calling to Mark, anxious for him to answer and tell me what was going on. I was afraid to hang up and try to send him help, but I also afraid not to. After a while, I could hear Mark speaking again, but his voice was shaking and disjointed, like he was disoriented in some way. The background noise was gone. After what seemed like a long time, Mark was able to tell me that a fire truck had passed by with its LED lights flashing, driving right by the car where he sat. From what I heard, by the abrupt onset, jolt, arc and character of the event, it reminded me of some sort of brain seizure. I have epilepsy and I've had seizures myself and witnessed seizures in family members and in my students. The way that Mark was left disoriented and finding it hard to speak was like symptoms of a seizure's aftermath. I stayed on the phone with him quite a while longer as he gradually recovered. It was a striking, terrible experience. Obviously much, much worse for him, but I felt badly shaken up. I have no doubt, either, that had I been in that park when the truck passed, I too would've suffered an equally sudden and severe reaction to that fire truck's flashers..I'm attaching an incident report with this letter to illustrate.

Sincerely,

MarieAnn Cherry

Washington County, New York

Exhibit E

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health

Form Approved:
OMB Number 0910-0025
Expiration Date: August 31, 2023
See Burden Statement on page 5.

ACCIDENTAL RADIATION OCCURRENCE REPORT

Note: Items with an asterisk (*) require a response.

SUBMITTER INFORMATION

If you are not submitting this report representing the manufacturing establishment for the radiation-emitting product causing the problem, you may enter your own company name under Establishment Identification and Submitter Address, or enter N/A and provide your home or other address.

Contact Information

Contact Name (Title, first name, last name)*

Mr. Mark Baker

Occupation Title

President

Email Address* mbaker@softlights.org

Establishment Identification (Manufacturer of the radiation-emitting product being reported, if known)

Establishment Name

Whelen Engineering

Division Name

Submitter Address

Address

Street* 9450 SW Gemini Drive PMB 44671

Telephone Number*

234-206-1977

City*

Beaverton

State*

OR

Zip Code*

97008

Fax Number

INFORMATION REGARDING PRODUCT MANUFACTURER

Product Manufacturer Name (If known)

Whelen Engineering Company Inc.

Product Manufacturer Address (If known)

Street (Line 1)

51 Winthrop Road

Street (Line 2)

City

Chester

Territory, Province, or State

CT

Country

USA

Zip or Postal Code

06412

Product Model Designation (If known)

Model Name or Number

Model Family Designation

Brand Name

Please provide any other information known regarding the manufacturer of the product that was involved in the accidental radiation exposure incident.

Liberty II and other product names. LED strobe light devices used by first responders such as police, fire, and ambulance.

If you are aware that the manufacturer was informed about the incident, please provide the contact information below.

Contact Information (Including whom you contacted and address)

custserv@whelen.com

Date Contacted

6/14/2022

PRODUCT INFORMATION

Product Types (Please select the best match (only one). Note that product types are grouped into radiation categories.)

<p>Acoustic Radiation</p> <ul style="list-style-type: none"><input type="checkbox"/> Therapeutic Ultrasonic Devices (Including diathermy and stimulators)<input type="checkbox"/> Ultrasonic Medical Devices (Miscellaneous) (Including lithotriptors)<input type="checkbox"/> Diagnostic Ultrasound Devices<input type="checkbox"/> Sonic Medical Products (Including hearing aids and vibrators)<input type="checkbox"/> Ultrasound Non-Medical Products (Including jewelry cleaners and intrusion security systems)<input type="checkbox"/> Sonic Non-Medical Products<input type="checkbox"/> Veterinary Diagnostic Ultrasonic Products<input type="checkbox"/> Veterinary Therapy Ultrasonic Products<input type="checkbox"/> Other Sonic or Ultrasonic Product	<p>Microwave EMF Radiation (Continued)</p> <ul style="list-style-type: none"><input type="checkbox"/> Microwave Identification, Safety, Security, and Surveillance Products<input type="checkbox"/> Industrial Dielectric Heaters<input type="checkbox"/> Microwave Medical Products<input type="checkbox"/> Microwave Heating and Drying Products<input type="checkbox"/> Microwave Communication, Data Transmit, and Measurement Products (Including CB radios, cell phones, walkie-talkies, household remote controllers)<input type="checkbox"/> Nuclear Magnetic Resonance Devices<input type="checkbox"/> Household ELF Products (Including electric blankets)<input type="checkbox"/> Other Microwave Product
<p>Ionizing Radiation</p> <ul style="list-style-type: none"><input type="checkbox"/> Personnel Security Systems (Including backscatter and transmission x-ray systems)<input type="checkbox"/> Cargo Non-Intrusive Security Systems<input type="checkbox"/> Cabinet X-Ray Systems, Non-Medical (Including baggage x-ray systems)<input type="checkbox"/> Industrial X-Ray Systems (Excluding Cabinet)<input type="checkbox"/> Analytical X-Ray Systems, Non-Medical<input type="checkbox"/> High Voltage Vacuum Switches<input type="checkbox"/> Industrial Particle Beam Systems<input type="checkbox"/> TVs and video monitors (Not including flat-screen TVs)<input type="checkbox"/> Medical Diagnostic X-Ray Equipment<input type="checkbox"/> Dental Diagnostic X-Ray Equipment<input type="checkbox"/> Therapeutic X-Ray Systems<input type="checkbox"/> Veterinary X-Ray Systems<input type="checkbox"/> X-Ray Bone Densitometers<input type="checkbox"/> X-Ray Film and Film Processing Materials<input type="checkbox"/> Cabinet X-Ray Systems, Medical<input type="checkbox"/> Medical Accelerators<input type="checkbox"/> Non-Medical Accelerators<input type="checkbox"/> High Voltage Vacuum Tubes<input type="checkbox"/> Cathode Ray Tube (Without Electronics Chassis)<input type="checkbox"/> Cold-Cathode Gas Discharge Tubes<input type="checkbox"/> Other X-Ray Product	<p>Optical Radiation</p> <ul style="list-style-type: none"><input type="checkbox"/> Medical Laser Products (Including surgical devices and laser therapy)<input type="checkbox"/> Surveying, Leveling, Alignment Laser Products (Including laser pointers, laser levels)<input type="checkbox"/> Laser Light Show/Display Products<input type="checkbox"/> Toy, Novelty, Play Laser Products<input type="checkbox"/> Safety, Security, Surveillance Laser Products (Including night vision systems, traffic speed systems and intrusion detection systems)<input type="checkbox"/> Research, Scientific, Laboratory Laser Products<input type="checkbox"/> Material Processing Laser Products (Including welders, cutters, engravers)<input type="checkbox"/> Data Measurement, Transmit, Control Laser Products (Including fiber optic communication systems, laser vision systems and process control systems)<input type="checkbox"/> Utility/Peripheral Laser Products (Including laser printers, bar code scanners, CD and DVD systems)<input type="checkbox"/> In Vitro and Other Medical Laser Products (Including Veterinary devices)<input type="checkbox"/> Patient Positioning Medical Laser Products<input type="checkbox"/> Other Laser Products<input type="checkbox"/> Sunlamp Products (Including sunlamps and tanning beds)<input type="checkbox"/> Mercury Vapor Lamps<input type="checkbox"/> Ultraviolet Medical Products<input type="checkbox"/> Ultraviolet Commercial/Consumer Products<input type="checkbox"/> Ultraviolet Surveillance & Detection Products<input type="checkbox"/> Ultraviolet Hygiene Products (Including UV sanitizers)<input type="checkbox"/> General Optical Products, Medical (Including surgical lamps)<input checked="" type="checkbox"/> General Optical Products, Non-Medical (Including LEDs and fluorescent lamps)
<p>Microwave EMF Radiation</p> <ul style="list-style-type: none"><input type="checkbox"/> Microwave Ovens (Food Prep)<input type="checkbox"/> Microwave Hyperthermia Therapy Devices<input type="checkbox"/> Microwave Diathermy Machines	

PRODUCT INFORMATION (Continued)

Product Description

Description of product and its intended use

LED strobe light that is intended to command people away from emergency vehicles.

ACCIDENTAL RADIATION OCCURRENCE INFORMATION

Location of Occurrence

Please provide the physical location where the Accidental Radiation Occurrence took place (e.g., at a residence, a factory, a tanning salon, school, restaurant, airport, etc.). If you do not know the exact address, provide responses to the best of your ability, or enter "Unknown."

Location or Establishment Name

Highway 99, Ashland, OR

Specific Section of Location or Establishment (If applicable)

Highway 99 at South Valley View Road

Address

Street

Telephone Number

City

State

Zip Code

Fax Number

Date of Event*

From

To

Web Address

Persons Involved

Number of people exposed in the Accidental Radiation Occurrence*

Number of people adversely affected*

Number of unexposed people who were involved*

Number of potentially exposed people who have not exhibited any adverse reactions*
Dozens

Dozens

2

Type of reportable event

Death

Serious Injury

Malfunction

Other

_____ .

Description of the nature and magnitude of exposure and/or injuries

The Ashland and Medford, OR emergency services responded to a vehicle crash at the corner of Highway 99 and South Valley View Road and used what I believe to be were Whelen Engineering LED strobe lights. When I came to the intersection in my vehicle, I was immediately overwhelmed neurologically by the pulsing LED visible radiation emitted by the LED strobe devices. I began to physically tremble and became emotionally shaken. By the time I reached home a few minutes later, I had a nervous breakdown consisting of uncontrollable sobbing.

ACCIDENTAL RADIATION OCCURRENCE INFORMATION (Continued)

Description of the Radiation Occurrence

Is this a new Accidental Radiation Occurrence (ARO) report or a supplement to a previous ARO report filed by you or your organization? (Please select one.)*

New ARO report

Supplement to previous ARO report (Enter date of previous report below.)

Date of previous ARO report, if applicable (mm/dd/yyyy) (Required entry* only if "Supplement to previous ARO report" is selected.)

Description of circumstances surrounding the accidental radiation occurrence (Please include a description of the activities leading up to the event and actions that occurred during the event, as well as any suspected causes of the occurrence.)*

This radiation event occurred due to emergency services using unregulated strobing LED visible radiation devices at the scene of a vehicle crash. Multiple emergency vehicles were involved, with each vehicle using about a dozen LED strobe devices.

Actions Taken

The actions described below are those taken to control, correct, or eliminate the causes and to prevent reoccurrence. If unknown, you may state "Unknown" below.

Description of specific actions, to date, taken by the manufacturer in response to the Accidental Radiation Occurrence*

I have contacted the cities of Ashland and Medford, and Whelen Engineering about this incident and previous incidents and they have chosen to either not respond or take no action to protect the public.

ACCIDENTAL RADIATION OCCURRENCE INFORMATION (Continued)

Actions Taken (Continued)

Description of future actions to be taken by the manufacturer, if known, in response to the Accidental Radiation Occurrence (*If this is a preliminary ARO report from the manufacturer, please indicate that further investigation is ongoing.*)*

Whelen Engineering has not indicated that they are willing to take any actions to protect the public or first responders from LED visible radiation.

If this involved a medical device, has a Medical Device Report (MDR) been submitted to FDA?*

Yes No N/A Unknown

Other Important Information (Please enter below)

Feel free to send in medical documentation regarding the incident and injuries.

Please mail this completed FORM FDA 3649 to the address to the right:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 2 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

*“An agency may not conduct or sponsor,
and a person is not required to respond to, a
collection of information unless it displays a
currently valid OMB number.”*