BEFORE THE U.S. FOOD AND DRUG ADMINISTRATION

PETITION FOR RULEMAKING TO REGULATE LIGHT EMITTING DIODE VEHICLE LIGHTS

SUBMITTED BY
SOFT LIGHTS FOUNDATION
ON
SEPTEMBER 6, 2023

CITIZEN PETITION

The undersigned submits this petition under CFR Title 21, Chapter I, Subchapter A, Part 10.25 and 10.30 to request the Commissioner of Food and Drugs to issue CFR Title 21, Chapter I, Subchapter J, Part 1040.50 - LED Vehicle Lights.

A. ACTION REQUESTED

Petitioner requests that the Commissioner 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.

B. STATEMENT OF GROUNDS

I. Introduction and Summary

The National Highway Traffic Safety Administration regulates vehicle lighting via Federal Motor Vehicle Safety Standard Section 108.[1] However, the Congressional authority to regulate

[1] https://www.ecfr.gov/current/title-49/subtitle-B/chapter-V/part-571/subpart-B/section-571.108

electromagnetic radiation from electronic products, including visible light, rests with the Food and Drug Administration as per 21 U.S.C. 360hh – 360ss. NHTSA has no Congressional authority to regulate Light Emitting Diode sources and thus NHTSA FMVSS-108 cannot be used to regulate LED vehicle lighting. NHTSA, the automakers, and aftermarket suppliers are dependent on the FDA to publish the performance standards for LED light sources used on vehicles.

For the purposes of this petition, LED vehicle lighting includes headlamps, taillights, brake lights, turn signals, flashing lights, Daytime Running Lights, backup lights, and all other external light sources on vehicles.

Lighting sources can be categorized by radiation type: Incoherent, Partially Coherent, and Fully Coherent. Table 1 shows a comparison of some of the differences between different types of radiation sources.

Vehicle Lighting Comparison by Radiation Type			
Radiation Type	**Incoherent**	**Partially Coherent**	**Fully Coherent**
Example	Tungsten Filament	Light Emitting Diode	Laser
Dispersion	Inverse Square Law	Directed Lambertian	Collimated
Metric Name	Luminous Intensity	Luminance	Radiance
Metric Units	Candela	Candela / m^2	Watts / m^2 / steradian
Hazard Level	Low	High	High
Regulations / Standards	NHTSA FMVSS-108	None	FDA 1040.10
Discriminatory	Low Possibility	Yes	Yes

Table 1 – Vehicle Lighting Comparison by Radiation Type

As can be seen in Table 1, NHTSA has authority and sets standards for incoherent light sources that are not emitted by an electronic product. The FDA has established regulations for laser products via 21 C.F.R. 1040.10, as shown in the right column. However, the FDA has not established regulations for LED products. The Soft Lights Foundation submitted citizen petition FDA-2022-P-1151 to the FDA on June 13, 2022, requesting that the FDA publish 21 C.F.R. 1040.40 - LED Products.[2] The FDA has not acted on that petition, and thus there are no performance standards for any LED product, and there are no performance standards for LED vehicle lights.

This petition requests that the FDA formulate rules that regulate and restrict the spatial, spectral, and temporal properties of the visible radiation emitted by LED vehicle lights to protect the comfort, physical health, neurological health, psychological health, cognitive functioning, vision, and safety of the public, to eliminate the discriminatory barriers created by LED vehicle lights, and to ensure that the civil rights of citizens are not violated.

II. Statement of Facts

A. Examples of LED Headlights

Because of the lack of FDA regulation of LED vehicle headlights, the automakers have been unconstrained. The result is vehicles that use LED headlights which cause blinding glare, as shown in the examples below.

[2] https://www.regulations.gov/document/FDA-2022-P-1151-0001

Figure 1 - LED Headlights

Figure 2 - LED Headlights

Here is a link to a video showing a motorist being blinded by LED truck headlights, and then crashing into an obstruction in the road. (https://tinyurl.com/4mtb9d53)

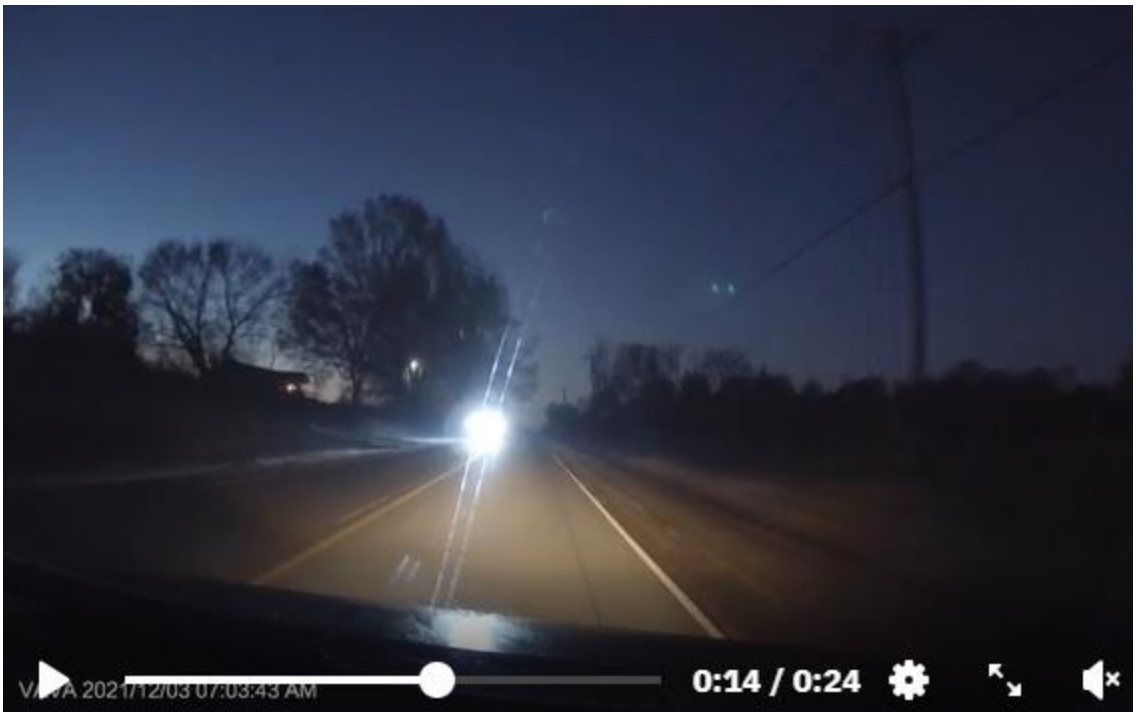

Figure 3 - LED Truck Headlights

B. Warnings On Other LED Products

The operator's manual for the Ryobi P705 Flashlight includes the following: "**WARNING: Do not direct the light beam at persons or animals and do not stare into the beam yourself (not even from a distance) Staring into the light beam may result in serious injury or vision loss.**" The parenthetical "(not even from a distance)" indicates that Ryobi is aware that LEDs emit dense directed energy that has little dispersion, even at long distances, and that LED visible radiation does not gently disperse.

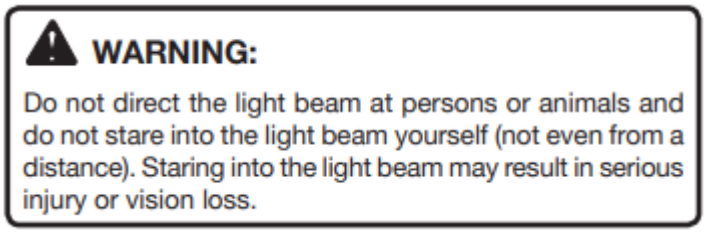

Figure 4 - Ryobi P705 LED Flashlight Warning

This LED light that Ryobi warns can cause serious injury or vision loss is the same light that the automakers are using for headlights, and which currently has no regulations from either NHTSA or the FDA.

C. Food and Drug Administration Authority

i. Regulation of Electromagnetic Radiation

In 1968, Congress passed the Radiation Control for Health and Safety Act, codified as 21 U.S.C. 360hh - 360ss, directing and authorizing the Food and Drug Administration to regulate electromagnetic radiation from electronic products. Electromagnetic radiation is categorized by frequency. While humans have managed to harness this radiation, the radiation can also be harmful to human health. In the US, the federal agency responsible for setting comfort, physical health, neurological health, psychological health, and safety standards for electromagnetic radiation is the FDA. As can be seen in Figure 5, this includes radiation on the human visible portion of the spectrum. Light Emitting Diode products are electronic products that emit visible radiation, and thus it is the duty and responsibility of the FDA to set protective standards.

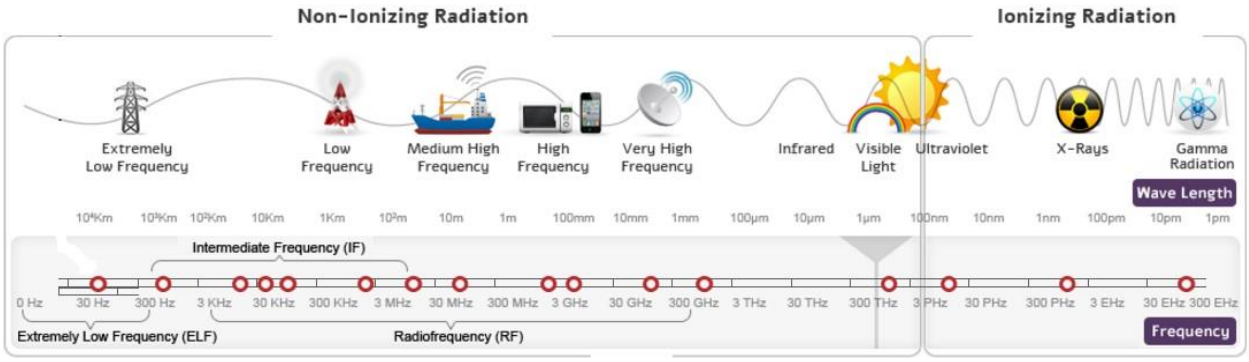

Figure 5 - Electromagnetic Spectrum[3]

ii. Title 21 Code of Federal Regulations

The FDA has confirmed that they have the authority and imperative to regulate LED visible radiation by issuing CSMS# 17-000330 - LIGHT-EMITTING DIODE (LED) REPORTING TO FDA on June 6, 2017, which states, "*FDA has regulatory authority over radiation-emitting electronic products, which are defined in 21 CFR 1000.3 as any electrically-powered product that can emit any form of radiation on the electromagnetic spectrum. As such, reporting to FDA upon importation of radiation-emitting electronic products is required. LED products emit visible optical radiation, which qualifies them to be radiation-emitting electronic products and gives FDA regulatory authority.*"[4] The FDA presentation How to Get Your Electronic Product on the U.S. Market details the authority of the FDA to regulate the radiation from electronic products and the requirements of manufacturers to submit reports to the FDA for their electronic products that emit radiation.[5]

The FDA has published Title 21, Chapter I, Subchapter J – Radiological Health, Parts 1000 – 1040 in the Code of Federal Regulations which details the requirements for products that emit electromagnetic radiation. What is missing from these regulations are the requirements for LED

[3] https://www.tnuda.org.il/en/physics-radiation/what-radiation/electromanetic-radiation-spectrum
[4] https://content.govdelivery.com/accounts/USDHSCBP/bulletins/1a00f8a
[5] https://www.fda.gov/media/88417/download

products. 21 C.F.R. 1000.15 categorizes and lists many products that emit radiation, including ovens, dryers, lasers, televisions, x-ray machines, and alarm systems. However, there is no mention of any LED products in this section such as LED vehicle lights, LED streetlights, LED General Service Lamps, LED indicator lights, etc. Similarly, 1002.1 lists products which require reports from the manufacturer, including laser products, sunlamps, and mercury vapor lamps. Which is missing from 1002.1 is any mention of LED products. Also, the FDA has published Part 1040 – Performance Standards for Light-Emitting Products, which includes 1040.10 – Laser, 1040.11 – Specific Laser Products, 1040.20 – Sunlamp Products and Ultraviolet Lamps Intended for Use in Sunlamp Products, and 1040.30 – High-intensity Mercury Vapor Discharge Lamps. The FDA has not published 1040.40 – Laser Products, 1040.41 LED Strobing Lights, 1040.50 LED Vehicle Lights, or any other Part in 21 C.F.R. that describes the performance standards for LED products.

iii. Congressional Authority

No federal agency has claimed that they have Congressional authority to regulate LED products. All responses sent to the Soft Lights Foundation from federal agencies have indicated the same position, which is that the only federal agency with Congressional authority to regulate LED products is the FDA.

NHTSA - The National Highway Traffic Safety Administration wrote to the Soft Lights Foundation on December 2, 2022, stating, "*NHTSA, as an agency focused on automotive safety, also recognizes the expertise of its sister agencies that are health-focused, such as the FDA*."[6]

Access Board - The Access Board sent a similar letter to the Soft Lights Foundation on August 21, 2023, stating "*The Access Board must deny this petition as the Board has no authority*

[6] https://www.softlights.org/wp-content/uploads/2022/12/NHTSA-220815-006_ND.pdf

under 21 U.S.C. §360ii either to initiate rulemaking or to require the FDA, were they to do so, to coordinate with the Access Board."[7]

FHWA - In a letter to the Soft Lights Foundation on October 19, 2022, the Federal Highway Administration Office of Civil Rights stated, "*The allegations you have raised about the health impacts of RRFBs raise complex issues related to the regulation of all Light Emitting Diode (LED) lights, not just those used in RRFBs, that extend beyond FHWA's authority.*"[8] The reference for regulation of LEDs is to the FDA. The FHWA thus acknowledges that it has no authority to regulate LED products and the letter implies that the FHWA understands that the FDA is the federal agency with authority to regulate LED products.

CPSC – The letter from the Consumer Product Safety Commission to the Soft Lights Foundation on November 7, 2022, states, "*The Commission shall have no authority under this chapter to regulate any risk of injury associated with electronic product radiation emitted from an electronic product*"[9]

EPA – In a letter dated October 7, 202, the Environmental Protection Agency stated, "*Congress has not granted the EPA any statutory authority to regulate visible light or non-ionizing radiation that is emitted from electrical devices, including LEDs. "*[10]

OSHA – The Occupational Safety and Health Administration wrote, "*DSG staff will also continue to stay apprised of this topic and any new scientific developments on hazards posed by LED devices in the workplace.*"[11] This letter indicates that OSHA is waiting for the FDA to notify OSHA of the hazards posed by LED devices.

[7] https://www.softlights.org/wp-content/uploads/2023/08/Response-to-Petition-for-Rulemaking_8-21-23.pdf
[8] https://www.softlights.org/wp-content/uploads/2022/10/Baker-CL-2022-0375.pdf
[9] https://www.softlights.org/wp-content/uploads/2022/11/CPSC-Jurisdiction-Response.pdf
[10] https://www.softlights.org/wp-content/uploads/2022/10/CMS-AX-22-000-1287-Response.pdf
[11] https://www.softlights.org/wp-content/uploads/2022/10/Letter-From-OSHA.pdf

FAA – On November 9, 2022, the Federal Aviation Administration wrote "*We would defer to the FDA for comfort, health, and safety regulations and to OSHA for specific topics like cockpit lighting, in regard to LED products.*"[12]

With all other federal agencies deferring to the FDA for performance standards for LED products, this creates a massive responsibility for the FDA to regulate everything from LED vehicle lights to LED General Service Lamps to LED indicator lights on appliances to LED flashing lights on emergency vehicles. The FDA now becomes responsible for setting standards for federal agencies that regulate traditional light sources. For example, NHTSA issued FMVSS-108 for vehicle lighting, including restrictions on maximum luminous intensity, number of allowed headlights, light color, etc. This responsibility now falls to the FDA for LED vehicle lights. As another example, the EPA states that they have no authority to regulate light pollution from LEDs, and that this responsibility now falls to the FDA when the source of the light pollution is an LED product.

The Soft Lights Foundation does not necessarily agree with the regulatory system as it exists now, with the FDA being the sole federal agency responsible for regulating so many LED products. A better system would seem to be to continue having NHTSA regulate headlights and the EPA regulating light pollution and OSHA regulating worker safety and the Access Board setting equal access standards related to LED radiation, but it appears that it would require an act of Congress to change the current system. As it exists now, the FDA is mandated by 21 U.S.C. 360hh – 360ss to regulate all products that use LEDs.

iv. 21 U.S.C 360hh – 360ii

[12] https://www.softlights.org/wp-content/uploads/2023/09/Jurisdiction-Letter-from-FAA.pdf

The Radiation Control for Health and Safety Act and subsequent updates to the law are codified in 21 U.S.C 360hh – 360ss. These statutes direct the FDA to regulate electromagnetic radiation to protect the public in the form of performance standards.

21 U.S.C. 360kk(a)(1) states, "*The Secretary shall by regulation prescribe performance standards for electronic products to control the emission of electronic product radiation from such products if he determines that such standards are necessary for the protection of the public health and safety.*" 21 U.S.C. 360ii(a) states, "*The Secretary shall establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation.*" 21 U.S.C. 360ii(a)(2) states, "*plan, conduct, coordinate, and support research, development, training, and operational activities to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation*". Taken together, these statutes make clear that Congress directs the FDA to minimize emissions of radiation from LED products, minimum exposure of the public to radiation from LED products, and protect the public's physical health, neurological health, psychological health, and safety from the harms of LED radiation.

v. Prohibition of LED Headlights and LED Daytime Running Lights

There is no mandate from Congress that automakers must use or be allowed to use LEDs for vehicle lighting. The automakers simply started manufacturing vehicles with LED headlights and LED Daytime Running Lights and NHTSA never stepped in to require the automakers to comply with the Administrative Procedure Act of 1946 to petition NHTSA or the FDA for authorization to use LED headlights and LED DRLs. NHTSA also refuses to recall vehicles with unregulated LED headlights, despite petitions from the Soft Lights Foundation to do so.[13]

[13] https://www.softlights.org/wp-content/uploads/2022/12/NHTSA-220815-006_ND.pdf

21 U.S.C. 360hh – 360ss requires that the FDA minimize the public's exposure to LED radiation and to ensure the protection of public health and safety. Unless the evidence shows that LED headlights and LED Daytime Running Lights and LED taillights and LED turn signals are safe for everyone, including those with epilepsy, autism, migraines, PTSD, and other neurological sensitivities, then the FDA must simply prohibit the use of LEDs for those vehicle systems. By publishing restrictions and prohibitions of vehicle lighting in 21 C.F.R. 1040.50, the responsibility for regulating non-LED vehicle lighting would fall back to NHTSA and FMVSS-108.

21 U.S.C. 360ii(a)(6)(B) directs the FDA to consult and maintain liaison with "*appropriate Federal departments and agencies*" (in this case, NHTSA), in "*the development of performance standards pursuant to section 360kk of this title to control such radiation emissions.*"[14] In this case, the FDA is required to consult and liaise with NHTSA to develop performance standards for LED vehicle lights and determine if it is even possible to make LED headlights and LED Daytime Running lights that do not trigger seizures, migraines, panic attacks, anxiety, fear, or agitation, cause eye pain or eye injury, or interfere with vision or cognitive functioning.

If the FDA determines that LED products can be used without adverse physical, neurological, psychological, or civil rights impacts on visual freedom, then the following sections detail the metrics that must be regulated for LED lighting on vehicles.

D. Luminance

The key metric for regulating radiation emitted from a flat surface is called 'luminance' which has the units of 'candela per square meter', also known as 'nit' in the industry. Luminance is a measure of the density of light. The equivalent radiological term is 'radiance' measured in 'watts per square meter per steradian'.

[14] https://www.law.cornell.edu/uscode/text/21/360ii

While the radiance metric is typically used to set regulations for photobiological safety to protect from chemical and thermal damage, the luminance metric is typically used for dazzle, glare, discomfort, distraction, vision, perception, cognitive functioning, neurological impacts, and psychological impacts.

NHTSA standard FMVSS-108 makes no mention of the metric luminance or radiance. Thus, even if NHTSA had Congressional authority to regulate LED vehicle lights, the FMVSS-108 standard contains no regulations for flat surface sources and no restrictions on peak luminance or radiance. The FDA's performance standards for LED vehicle lights will need to set limits on peak luminance.

There is no known definitive study for setting the upper limit on peak luminance from an LED source, but a study funded by the Epilepsy Foundation of America and published in the journal Epilepsia on February 27, 2022 suggests that this limit is 20 candela per square meter.[15]

E. Dispersion Characteristics

LEDs emit light in a directed energy beam that does not follow the same dispersion pattern as a traditional light source such as a tungsten filament. While there is a semantical debate as to whether the light emitted by radiation follows an inverse square law, multiple sources state that only radiation emitted by point sources comply with the inverse square law.[16,17] Since LEDs are Lambertian sources, not point sources, the light emitted by LEDs does not gently disperse following an inverse square law, but instead diverges slowly, maintaining its peak intensity even at long distances. The FDA must ensure that LED vehicle light sources

[15] https://onlinelibrary.wiley.com/doi/10.1111/epi.17175
[16] http://hyperphysics.phy-astr.gsu.edu/hbase/Forces/isq.html
[17] https://en.wikipedia.org/wiki/Inverse-square_law

diverge and disperse in a manner consistent with point source characteristics to ensure public comfort, health, safety, and visual freedom.

F. Spatial Uniformity

LEDs emit light almost solely in the forward plane and this light does not have uniform spatial energy. The mathematical shape of LED light is called a Lambertian.[18] LEDs have an inherent lensing property due to the flat surface emitter. Light that is spatially non-uniform is unsafe because it is more difficult for the nerves and brain to process. The FDA must set quality requirements for the spatial distribution of LED vehicle light sources.

G. Spectral Power Distribution

Blue wavelength light has been well documented to be a photobiological hazard as well as causing dangerous glare. Yet, the automakers currently manufacture their vehicles with 6500K LED headlights and Daytime Running Lights, putting the public at risk of suffering acute and cumulative eye damage which is irreversible. The use of Correlated Color Temperature is not a precise enough metric to protect the public, and thus the FDA must specify restrictions for spectral power distribution to ensure the comfort, health, and safety of both drivers and pedestrians.

H. Digital Flicker

LED vehicle lights may exhibit digital flicker because of the electronics that drive the LED. The FDA must set standards, such as requiring less than 5% flicker and requiring a sine-wave shape.

I. Pulse Width Modulation

[18] https://ieeexplore.ieee.org/document/8879542

The automakers may use Pulse Width Modulation to dim the LED lights, which thus creates a deliberate flicker. Certain individuals can see this flicker consciously, which is psychologically hazardous, and which impairs driver vision. Even for individuals who do not notice the flicker consciously, there is a significant adverse neurological impact which can lead to headaches, annoyance, agitation, or exhaustion. The FDA must set restrictions on the use of PWM to ensure the comfort of all drivers and pedestrians.

J. Flashing Characteristics

NHTSA does not currently regulate flashing lights. This regulation has been left up to the individual States. However, because the FDA is mandated by Congress to protect the public from electromagnetic radiation and to minimize exposure to such radiation, the FDA must now set restrictions on LED flashing and strobing lights. In general, the intensity of LED flashing lights is simply too hazardous to be allowed for use on vehicles. As mentioned earlier, the research review in the Epilepsia article noted that any flashing with a luminance above 20 candela per square meter is a risk for individuals with epilepsy. For individuals with autism, LED flashing lights will grab that individual's attention, causing anxiety and stealing the individual's right to visual freedom. The FDA's regulations for flashing lights must ensure that the light does not flash digitally or with an intensity that can cause adverse neurological reactions, impair vision, reduce cognitive functioning, or violate civil rights.

K. Distraction

Because of the properties of LED light, drivers and pedestrians can become distracted by the LED light, creating unsafe conditions. The FDA must restrict LED vehicle lighting to ensure that the light performs the stated purpose, such as illumination of the roadway, without causing distraction. LED Daytime Running Lights most likely must be prohibited entirely, as LED DRLs are

a significant source of distraction and there are no known studies that show that LED DRLs provide any benefits.

L. Vision

Drivers are taught to always scan the roadway ahead and to the sides and even behind to be aware of potential hazards. LED light sources impair driver vision due to glare, attention capture, flashing, or intensity. The FDA must set restrictions on LED vehicle lights to ensure that driver vision is not impaired by their use.

M. Neurological Impacts

LED radiation can trigger seizures, migraines, panic attacks, nausea, headaches, and other adverse neurological reactions. The FDA's performance standards will need to ensure that the most sensitive individuals do not suffer these adverse neurological impacts when exposed to LED vehicle lights.

N. Psychological Impacts

LED radiation can cause agitation, anger, fear, anxiety, and other psychological impacts. The intensity of the radiation, the unnatural spectral power distribution, the Lambertian spatial shape, and the digital flicker can cause serious adverse emotional reactions. The FDA's performance standards will need to ensure that the most sensitive individuals do not suffer these adverse impacts when exposed to LED vehicle lights.

O. Civil Rights Claims

The lack of FDA regulations for dangerous and discriminatory LED lights has already led to multiple claims of discrimination. Discrimination is prohibited by the Americans with Disabilities Act, codified as 42 U.S.C. Chapter 126.[19] On June 15, 2023, the Minnesota

[19] https://www.law.cornell.edu/uscode/text/42/chapter-126

Department of Human Rights issued a finding in a case involving high-luminance LED flashing lights, stating that there was probable cause for discrimination.[20] Another RRFB ADA claim has been made in Williamstown, Massachusetts. An LED civil rights claim has been made to the New York State Human Rights Commission, Case 10212383.

LED lights violate citizen's right to visual freedom. While the idea that LED lights restrict visual freedom may be a new idea, and lacking extensive legal case histories, it should not be difficult to realize that directing unregulated, high intensity, partially coherent visible radiation into the eyes of citizens is a violation of basic human and constitutional rights.

P. Public Petition

Nearly 50,000 people have signed the petition titled Ban Blinding Headlights and Save Lives![21] The petitioners have submitted thousands of comments, alerting NHTSA and the FDA to the hazards of LED headlights. These comments are found in Appendix A of this petition.

III. Conclusion

In summary:

1. LED vehicle lights are unvetted, unregulated, unapproved, hazardous, dangerous, discriminatory and their use violates fundamental civil rights.
2. LED vehicle lights have been shown to cause serious harm and injury, including nausea, panic attacks, seizures, reduced cognitive functioning, impaired vision, eye pain, and eye injury.
3. LED vehicle lights are discriminatory, violating ADA prohibitions against discrimination and ADA requirements of equal access.

[20] https://www.softlights.org/wp-content/uploads/2023/06/74059-6-15-2023-ECP-Memorandum-.pdf
[21] https://www.change.org/p/u-s-dot-ban-blinding-headlights-and-save-lives

4. LED vehicle lights violate basic civil rights such as the right to visual freedom.
5. The FDA is mandated to publish performance standards for LED vehicle lights, as per 21 U.S.C. 360ii and is required to liaise with NHTSA on the development of these standards.
6. The FDA is the sole federal agency with Congressional authority to regulate LED vehicle lights.

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

C. ENVIRONMENTAL IMPACT

Few, if any, biological creatures have evolved to endure intense directed energy visible radiation. LED lights are thus having a massive negative impact on the biological systems that inhabit the environment. FDA regulation of LED radiation is of utmost importance.

D. ECONOMIC IMPACT

To be submitted only when requested by the Commissioner.

E. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

/s/ Mark Baker

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