UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Petition for the regulation of Light Emitting Diode Products	Docket No. _____
	Petitioner: Soft Lights Foundation
	Date: June 13, 2022

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 1040.40 Light Emitting Diode products.

A. ACTION REQUESTED

Petitioner requests that the Commissioner issue 21 CFR Part 1040.40 to regulate electromagnetic radiation in the visible portion of the spectrum emitted by products that use Light Emitting Diodes and that these regulations set restrictions on spatial non-uniformity, chip-level peak luminance and peak radiance, spectral power distribution, and square wave flicker and that the regulations be designed to protect the physical and psychological health, safety, comfort, and civil rights of those who are negatively impacted by LED light.

B. STATEMENT OF GROUNDS

I. Introduction

In 1968, Congress passed the Radiation Control of Health and Safety Act which directed the Food and Drug Administration to regulate electronic products and the electromagnetic radiation emitted by those products, including visible light. The FDA issued Title 21, Part I, Subchapter J, Part 1040 in the Code of Federal Regulations which is titled Performance Standards for Light-Emitting Products. The FDA has issued 21 CFR Part 1040.10 Laser products., Part 1040.20 Sunlamp products and ultraviolet lamps intended for use in sunlamp products., and Part 1040.30 High-intensity mercury vapor discharge lamps.

In 2018, the FDA posted the statement on the FDA's website, "*LEDs (Light Emitting Diodes) are different from laser diodes and are not subject to the Federal laser product performance standard.*"[1] This statement does not clarify whether LEDs have never been regulated by the FDA, or if the FDA had been previously regulating LEDs under Part 1040.10 but has now stopped regulating LEDs within Part 1040.10. In either case, this lack of regulation of LEDs violates Congress' mandate in the 1968 Radiation Control of Health and Safety Act to regulate electromagnetic radiation.

LEDs were invented in the 1960s, so FDA regulation of Light Emitting Diodes should have occurred long ago. As we can see, however, Part 1040

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[1] https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/laser-products-and-instruments

Performance Standards for Light-Emitting Products is missing Subpart 1040.40 Light Emitting Diode products. This lack of FDA regulation of Light Emitting Diodes must be rectified.

II. Light Emitting Diodes

There are two types of light sources: point sources and surface sources.

Point source: A point source emits light from a curved surface which results in spatially uniform energy, and which can be modeled as a mathematical point. Brightness is measured with luminous intensity in candela. Examples include the sun, a candle, an incandescent light bulb, fluorescent, and High-Pressure Sodium.

Surface source: A surface source emits light from a non-curved, flat surface which results in spatially non-uniform energy, and which creates a Lambertian mathematical shape. Brightness is measured with luminance in nits (candela per square meter). An example is a Light Emitting Diode.

Cellular organisms and viruses have evolved with the uniform energy of point source light. The introduction of non-uniform energy from surface source devices has created new type of light. For humans and other biological systems, this surface source LED light is a low-quality light because of its spatial non-uniformity, piecewise spectral power distribution, and square wave flicker. The diagram below shows a comparison of the spatial, spectral, and temporal properties of point source versus surface source light.

Incandescent vs. Light Emitting Diode (LED)

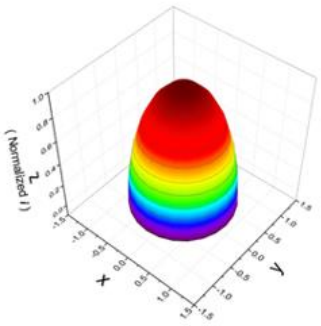
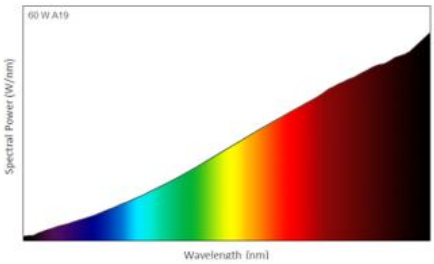
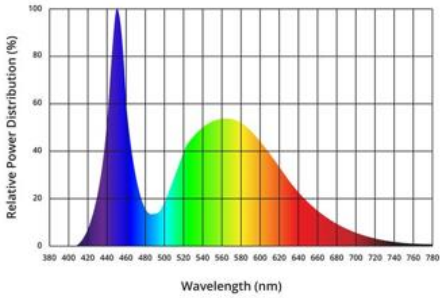
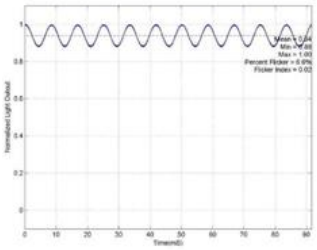
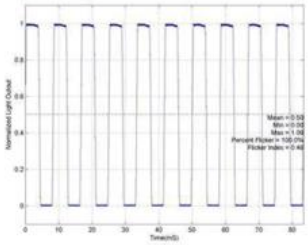
	High Quality Light Incandescent	Low Quality Light LED
Spatial		
	Uniform Luminance	Non-Uniform Luminance
Spectral		
	Low Blue Continuously Increasing	Blue Spike Piecewise
Temporal		
	Analog Sine Wave	Digital Square Wave

Figure 1 - Incandescent vs. LED

The Institute of Electrical and Electronics Engineers has published a peer-reviewed article by Dr. Nisa Khan that details the calculus mathematics used to describe the Lambertian shape of a flat-surface source.[2] Figure 2 from the IEEE article shows how light from a flat surface LED chip does not produce spatially uniform energy. This view is a 2D cross-section of 3D space.

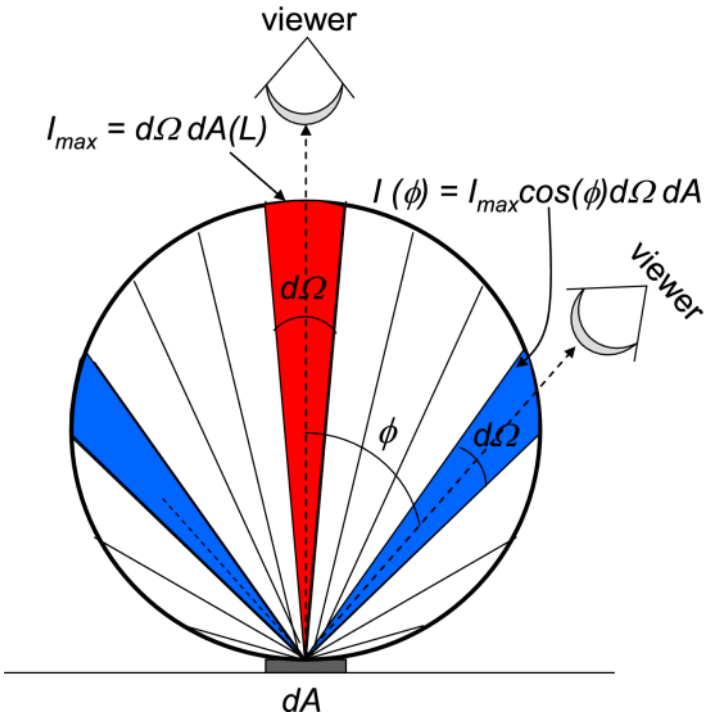


Figure 2 - Lambert's Cosine Law

This mathematical proof that LED light is spatially non-uniform is of utmost importance for the FDA's regulation of LED light. Until now, no government agency has understood that LED light has different energies and

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

characteristics at every point in 3D space and that previous formulas, calculations, and regulations that assumed uniform luminance cannot be used with LED light.

III. Health, Safety, and Comfort

The low quality of LED light has been shown to have significant negative impacts on human health, safety, and comfort, including causing epileptic seizures, migraines, panic attacks, nausea, loss of balance, reduced visual perception, anxiety, anger, agitation, and eye injury.

a. Neurological Health, Safety, and Comfort

The FDA must set standards that protect all members of the public, including those who are especially sensitive to LED light. It may be that LED light is so toxic that it cannot be used for the purpose of illumination. Just because there are already hundreds of millions of LED sources already in the environment does not justify setting standards that would continue to allow harm to members of the public who are sensitive to LED light.

The study Daily blue-light exposure shortens lifespan and causes brain neurodegeneration in Drosophila was published on October 17, 2019.[3] The study concluded that "*blue light may cause brain degeneration as well as*

[3] https://www.nature.com/articles/s41514-019-0038-6

retinal damage and reduce the lifespan."[4] This is extremely significant as many LED products emit excessive amounts of blue wavelength light.

There is a lack of formal, supervised study of the impacts of the spatially non-uniform energy of LED light on humans. However, there is significant documented evidence via personal stories of serious negative reactions to LED light that cannot be explained by the square wave flicker or blue wavelength light alone. LED light is very dense and yet within that density, the energy is non-uniform. Exactly how this effects our nervous system has not been formally studied in detail, and yet we already know the consequences from the telling of personal experiences.

MarieAnn Cherry testified to the New York State Public Service Commission on May 16, 2022.[5] Ms. Cherry opened her testimony by saying, "*I have epilepsy and migralepsy. I cannot neurologically tolerate any LED exposure, and I am thrown instantly into violent seizures from the briefest strike of LED light*." Ms. Cherry does not experience these seizures when exposed to incandescent or High-Pressure Sodium light. The difference is the spatially non-uniform energy from LEDs that trigger Ms. Cherry's seizures. These LED lights are currently used in public streetlights, preventing Ms. Cherry from using the public roads when these LED

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[4] https://www.news-medical.net/news/20191018/Blue-light-and-fruit-flies-a-warning-for-humans.aspx
[5] https://documents.dps.ny.gov/public/MatterManagement/CaseMaster.aspx?MatterCaseNo=21-02623&CaseSearch=Search

streetlights are turned on. The FDA must regulate LED products so that people like Ms. Cherry are protected from life-threatening seizures. This means setting health, safety, and comfort requirements for spatial uniformity, peak luminance and peak radiance, spectral power distribution, and square wave flicker.

Elaine Dennehy testified to the Irish Parliament on February 3, 2022.[6] Ms. Dennehy opened her testimony by saying, "*I thank the committee very much for this opportunity. I also hope that this can help, in many ways, the others who are suffering around the world from light emitting diode, LED, sensitivity and artificial light sensitivity. I have been made ill from LEDs since 2007. It is more than a sensitivity; it is a disability. I am disabled by my environment, like so many others, and excluded from society. This is also an accessibility issue*." The fact that the use of LED light excludes Ms. Dennehy from society is a serious concern. The FDA must understand the toxicity of spatially non-uniform LED light and its impacts on human nerves and consider these factors in the regulating of LED light.

Additional References:

1. NYSPSC Case Number 21-02623[7]
2. Soft Lights Foundation Documented Stories of LED Harm[8]

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[6] https://www.oireachtas.ie/en/debates/debate/joint_committee_on_disability_matters/2022-02-03/2/
[7] https://documents.dps.ny.gov/public/MatterManagement/CaseMaster.aspx?MatterCaseNo=21-02623&CaseSearch=Search
[8] http://www.softlights.org/stories/

3. LightAware Charity Documented Stories of LED Harm[9]

4. Soft Lights Foundation Collection of Research Articles[10]

b. Eye Health, Safety, and Comfort

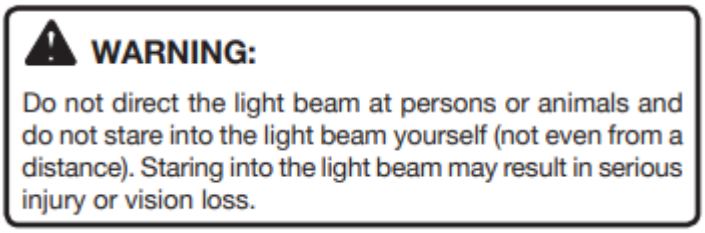
The energy from LEDs is measured both with luminance and radiance. The FDA must set maximum safety standards using both metrics. Standards should be set not just at the point where eye damage occurs, but also at the point where discomfort begins.

The company Fireflier published the article What is Photobiological Safety Standard? in April 2021[11]. The article concludes, "*the risks posed by these new sources of light are also rooted in their intrinsic characteristics: high optical output in a small package (producing a high radiance level) associated with significant blue light emission. The combination of these two factors can potentially increase the risk of photochemical damage of the retina, in comparison with the incandescent lamp and the fluorescent lamp*." FDA regulation of LED light is a necessity.

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**

[9] https://lightaware.org/about/individual-stories/
[10] https://www.softlights.org/resources/
[11] https://fireflier.com/what-is-photobiological-safety-standard/

distance) Staring into the light beam may result in serious injury or vision loss." The warning also refers to children, who along with infants are an identified high-risk population vulnerable to LED-exposure harm. Babies often lack an adult's automatic, self-protective aversion response to bright or intense light, and will stare directly at the source. The parenthetical "(not even from a distance)" indicates a high level of danger.



We wonder where Ryobi is getting their information about the dangers of LED light and how they chose to include "not even from a distance." LEDs emit very dense light that can travel long distances with very little dispersion, so Ryobi is correct about the dangers. But how can Ryobi sell a product that is known to be dangerous and has no FDA approval and no FDA regulations?

One of the unusual characteristics of LED light is that it will affect people from long distances away. Therefore, FDA regulation is not simply for the operator or user, but also for anyone who would be within several miles of the emitted light. The FDA must ensure the protection of those on the receiving end of the light who have no control over the operator's actions.

IV. Existing Standards for Illumination

Existing standards for illumination are based on point source light. These standards assume that the light is spatially uniform. An example is the Illuminating Engineering Society RP-8-18 Recommended Practice for Design and Maintenance of Roadway and Parking Facility Lighting was written for point source light such as High-Pressure Sodium. Because LEDs emit spatially non-uniform light, standards such as IES RP-8-18 cannot be used for LED products, and a new standard must be written that accounts for the spatially non-uniform light.

Cree Lighting is the first company in the industry to admit that the industry has been measuring LED light incorrectly.[12] Cree states, "*Not one of the existing metrics takes into account the non-uniform emitting surface of a LED luminaire.*" This statement is very important for the FDA to understand. Cree is stating what no agency in government has so far understood, which is that LED light is spatially non-uniform and that there are no measurement standards that are taking this spatial non-uniformity into account. Cree also writes, "*We also bring a call for urgency to this work. Without a speedy agreement on metrics for measuring LED intensity, photometry, and LED spacing, we will be installing millions of LED luminaires for street lighting*

[12] https://online.flippingbook.com/view/702884488/

purposes that are not suitable for use, could even be described as dangerous, and that will be costly to replace."

Existing devices that measure light in far-field cannot be used to measure surface light due to lack of precision and lack of firmware and software designed to process spatially non-uniform light.

V. Energy Efficiency Claim

The definition of **energy efficiency is providing the same quality of service using less energy**. This means that when LED light is compared against incandescent light, the light quality must be equivalent in order to state whether LED is more energy efficient than incandescent. Since LED light is spatially non-uniform, has a piecewise spectral power distribution shape, and has square wave flicker, the light quality of LED is much lower than the light quality of incandescent. Therefore, the claim that LEDs are more energy efficient than incandescent cannot be made because the two sources are not providing the same quality of service. LED light is simply a low-quality light. The FDA must issue a finding that makes it clear to the industry that LEDs cannot be claimed to be energy efficient.

VI. Affected Federal Agencies

Many federal agencies are affected by the FDA's lack of regulation of Light Emitting Diodes. Currently, not a single federal agency has developed regulations to protect the public health, safety, comfort, or civil rights from LED

light. It is likely that these agencies are first waiting for the FDA to set initial regulation, after which the other agencies would follow suit and develop regulations for LED light for the areas within their jurisdiction.

a. Department of Energy

The DOE was heavily involved in the development of high-powered LEDs for the illumination of a volume of space. However, the DOE has treated LED light and incandescent light as equivalent when they are not. The DOE has also ignored the research papers and personal stories of injury related to LED light.

In April 2022, the DOE publish a Final Rule on General Service Lamps that included references to General Service Light-Emitting Diode Lamps, and which phases out incandescent light bulbs on the false premise that LED light and incandescent light is equivalent. In the Final Rule for GSL's, the DOE did not mention that LED light products have not been approved or regulated by the FDA.

FDA regulation of LED products is needed so that DOE can properly regulate General Service Lamps and other light emitting products. An FDA finding that LED light is not equivalent to incandescent light and that LED light is not more energy efficient than incandescent light is especially important.

b. National Highway Traffic Administration

The NHTSA standard for regulating headlights is FMVSS-108 which was written in 1966. FMVSS-108 uses luminous intensity measured in candela to specify maximum brightness levels. This metric cannot be used for LED light since surface source brightness is measured with luminance in nits. Figure 3 shows an example of LED headlights.

Figure 3 - Vehicle Headlight

It should be clear to the reader that the light shown Figure 3 is dangerous. LED chip makers have exceeded 100,000,000 nits of peak luminance[13] and yet NHTSA has no regulations for spatial uniformity or peak luminance. The second light parameter that makes LED headlights

[13] https://www.laserfocusworld.com/test-measurement/research/article/16555223/nonlaser-light-sources-highluminance-leds-target-emerging-automotive-lighting-applications

dangerous is that the spectral power distribution used by the vehicle manufacturers has an excessively high peak at 450 nanometers, which is blue wavelength light. This is the wavelength that creates glare and is dangerous for the cells in the eye. A third parameter that makes LED headlights undesirable is the square wave flicker.

While many people seem to have a neurological saturation feature that causes them to merely state that LED headlights are "very bright", many other people do not saturate and are overwhelmed by the non-uniform luminance, the excessively high peak luminance, the high glare blue wavelength, and/or the square wave flicker. For many people, LED headlights cannot simply be tuned out, but rather these headlights are a dangerous distraction, inducing migraines, seizures, anger, and greatly reduced vision.

A petition to ban blinding headlights has over 30,000 signatures and comments. (https://www.change.org/p/u-s-dot-ban-blinding-headlights-and-save-lives). This is over 6 times the number of complaints that NHTSA has ever received for any issue in NHTSA's entire history.

FDA regulation of LED products is needed so that NHTSA can properly regulate headlamps and other light emitting products on vehicles by restricting spatial non-uniformity, peak luminance, spectral power distribution, square wave flicker. FDA findings that LED light cannot be regulated using luminous intensity and instead requires regulation of

luminance, and that LED light is not neurologically tolerable to some people are especially important.

c. Federal Motor Carrier Safety Administration

Commercial trucks often are older vehicles that have been retrofitted with LED headlights. These aftermarket LED headlights have no regulations from either NHTSA or the FMCSA which would ensure the safety, health, and comfort of commercial truck drives and the public.

FDA regulation of LED products is needed so that FMCSA can properly regulate headlamps and other light emitting products on commercial vehicles.

d. Federal Highway Administration

The FHWA has regulations for flashing lights on signs and publishes the Manual on Uniform Traffic Control Devices. However, the FHWA has not developed regulations for surface source LED flashing lights and has no limits on spatial non-uniformity, peak luminance, spectral power distribution, square wave flicker, or square wave flash characteristics.

FDA regulation of LED products is needed so that the FHWA can properly regulate LED flashing lights and other LED light emitted by traffic control devices.

e. National Transportation Safety Board

The NTSB investigates vehicle crashes and other transportation related incidents. Currently the NTSB does not take into consideration the impacts of spatially non-uniform LED light when investigating vehicle crashes. This non-uniform LED light could be from vehicle headlights, flashing lights, flood lights, streetlights, bicycle headlights or numerous other sources of LED light.

The NTSB is currently unable to measure the uniformity, peak luminance, spectral power distribution or flicker using the instruments they have because those instruments are not designed for the non-uniformity of surface source light and do not have the precision to measure quantities such as peak luminance in far-field conditions.

FDA regulation of LED products is needed so that the NTSB can develop crash site testing methodologies that can accurately account for LED light quantities such as peak luminance and spectral power distribution.

f. Consumer Product Safety Commission

The CPSC lacks safety standards for LEDs used in toys, appliances, power tools, and numerous other consumer products. For example, Figure 4 shows an LED display on a consumer washing machine. The CPSC has no maximums for peak luminance to ensure eye comfort and safety. Many LED displays are excessively bright, which can cause

discomfort and pain. For sensitive individuals, excessively bright LEDs may cause a seizure or migraine.

Figure 4 - Washing Machine LED Display

Figure 5 shows LEDs used on clothing. The photo makes it clear that the LED light is very sharp, which could injure the eye or cause emotional harm of another person.

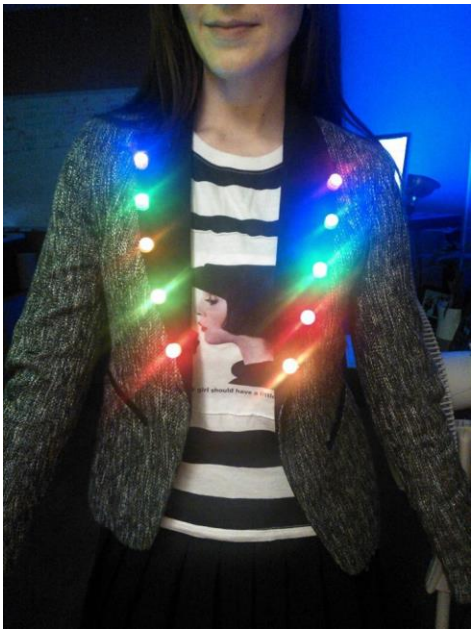


Figure 5 - LEDs on Clothing

Figure 6 shows an LED floodlight that is advertised as "30% brighter" with a luminous flux of 6000 lumens and a 5000 Kelvin color temperature. This is a dangerous light. The CPSC has no regulations to protect the consumer from this intense light. Since LED light can travel great distances with little dissipation, this LED light can adversely affect people up to several miles away. A product this powerful and dangerous must be regulated.

Figure 6 - LED Floodlight

The CPSC is reliant on FDA regulation of LED products to protect the health, safety, and comfort of consumers.

g. Department of Health and Human Services

LED light has been shown to cause epileptic seizures, migraines, panic attacks, nausea, malaise, anger, agitation, and eye damage and yet the HHS has no guidance for LED light. HHS is reliant on FDA regulation of LED products to protect the health, safety, and comfort of the public.

h. Federal Communications Commission

The images transmitted to display devices such as televisions now frequently show high-intensity LED light, which in turn is often shown in brief flashes on the screen. This intense LED light can cause negative neurological reactions, including migraines and seizures. Where the FCC may have previously required a warning at the beginning of a television show if the show displayed rapidly flashing light to warn people with epilepsy, the FCC has no regulations for LED light.

For example, the National Basketball Association arenas have installed LED overhead lights, LED displays, and LED colored lights for entertainment effect. However, because of the lack of regulation, these LED lights are overly intense, leading to audience reactions ranging from discomfort to pain to incapacitation. Other examples include advertising, perhaps showing LED headlights or rapidly switching between images.

The FCC needs FDA's regulation of LED products so that the FTC can develop its own regulations to protect the health, safety, and comfort of consumers.

i. Federal Trade Commission

LED lighting manufacturers, retailers, and utility companies falsely claim that LED light is equivalent to incandescent light or that LED light is energy efficient as compared to incandescent. These are false advertising claims.

FDA regulation of LED products is needed so that the FTC can hold these companies accountable for false advertising. An FDA finding that LED light is not equivalent to incandescent light and that LED light is not more energy efficient than incandescent light is especially important.

j. Access Board

LED light has created a new class of people who become disabled when exposed to LED light. The Access Board is mandated to develop guidelines to ensure that LED light-disabled people are protected from discrimination from the use of LED light but has not done so.

"LED light-disabled" is not a defined disability but is an additional disability on top of disabilities covered by the Americans with Disabilities Act such as those with epilepsy, autism, migraines, lupus, PTSD, and many others.

Clear findings from the FDA that LED light is disabling and can trigger epileptic seizures or other neurological reactions in people with

disabilities will provide the information the Access Board needs to develop guidelines for the use of LED light.

k. Occupational Safety and Health Commission

LED light has a tremendous impact on workers. OSHA has so far not developed any safety regulations for the use of LED light. Figure 7 shows the use of LED flashing lights on a police vehicle. The police are now using these intense, rapidly flashing LED lights, but without any safety regulations from OSHA.

Figure 7 - Police LED Flashing Lights

Figure 8 shows the use of LED office lighting. OSHA has no safety regulations for LED lighting and thus workers may be suffering eye strain, eye injury, headaches, or illness. It is documented that some workers have been forced out of the workplace due to the use of LED lights.

Figure 8 - LED Office Lighting

FDA regulation of LED products is needed so that OSHA can develop safety regulations to protect workers.

l. Environmental Protection Agency

LED light is having a massive negative impact on the ecosystem, leading to significant increases of light pollution, large declines of insects, and an overwhelming impact on human health. The natural night is a fundamental resource just like air and water. The EPA currently has no regulations for the protection of the natural night resource or the use of LED light in outdoor spaces.

Figure 9 shows the use of LED lights in a parking lot. The excessive and toxic blue wavelength light is visible in the photo. This light is

trespassing into neighboring houses, interrupting sleep, and is devastating for both diurnal creatures trying to sleep and nocturnal creatures trying to forage.

Figure 9 - LED Parking Lot Lights

The EPA needs FDA findings that show that LED light is a toxin that needs EPA regulation.

VII. Conclusion

Light Emitting Diodes emit an entirely different type of light than incandescent because the light is emitted from a flat surface, thus creating non-uniform luminance. In addition, LEDs have a piecewise spectral power distribution and square wave flicker. The quality of LED light is much lower than the quality of incandescent light. The low quality of LED light causes serious negative health effects, including seizures, migraines, and emotional trauma, as well as a high risk of eye injury. LED devices are not energy efficient because they don't produce the same quality of light as incandescent.

In just the past two decades, LEDs have proliferated across the world in almost unimaginably large numbers, almost entirely without regulation. This has led to very serious negative consequences for the health, safety, comfort, and civil rights of the public.

Congress has mandated that the FDA regulate electromagnetic radiation from electronic products, including visible light. Therefore, the FDA must quickly issue CFR 21 Part 1040.40 LED products and regulate spatial uniformity, peak luminance and peak radiance, spectral power distribution, and square wave flicker to ensure the health, safety, comfort, and civil rights of the public, especially those who are LED light-disabled.

C. ENVIRONMENTAL IMPACT

LEDs are having a massive negative impact on the environment and must be regulated by the EPA. The EPA actions are dependent on the FDA's regulation of LED products.

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.

Personal Information Redacted:

[redacted]