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EASTERN DISTRICT OF CALIFORNIA
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Mark Baker
9450 SW Gemini Dr. PMB 44671
Beaverton, OR 97008
Pro Se

BEFORE THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

COMPLAINT AND REQUEST FOR COERCIVE RELIEF
FDA AND NHTSA LIAISON FOR LED VEHICLE
HEADLAMPS

MARK BAKER,
Plaintiff,

vs.

UNITED STATES FOOD AND DRUG
ADMINISTRATION; MICHELLE TARVER,
in her official capacity as Acting Director of the
FDA Center for Devices and Radiological
Health; ROBERT M. CALIFF, in his official
capacity as Commissioner of Food and Drugs;
UNITED STATES HEALTH AND HUMAN
SERVICES; XAVIER BECERRA, in his
official capacity as Secretary of the Department
of Health and Human Services; UNITED
STATES NATIONAL HIGHWAY TRAFFIC
SAFETY ADMINISTRATION; SOPHIE
SHULMAN, in her official capacity as Deputy
Administrator of NHTSA; PETE BUTTIGIEG,
in his official capacity as Secretary of the
Department of Transportation; and UNITED

Case No.: 2:24 cv 02558
DJC JDP (ps)

STATES DEPARTMENT OF
TRANSPORTATION

Defendants.

I. COMPLAINT

1. Plaintiff, Mark Baker, alleges that the Food and Drug Administration (“FDA”) and the National Highway Traffic Safety Administration (“NHTSA”) have failed to comply with 21 U.S.C. 360ii(a)(6)(A) which requires the FDA and NHTSA to establish and maintain a liaison on techniques, equipment, and programs for testing and evaluating Visible Light radiation from Light Emitting Diode (“LED”) vehicle headlamps. In addition, the FDA has unlawfully dissolved the Technical Electronic Product Radiation Safety Standards Committee (“TEPRSSC”) which is mandated by 21 U.S.C. 360kk(f)(1)(A) as part of the Electronic Product Radiation Control Program of 21 U.S.C. Part C. Plaintiff requests that the Court order coercive relief.

II. PARTIES

2. Plaintiff is Mark Baker, a citizen of the United States of America.

3. Defendant FDA is an agency of the federal government within the United States Department of Health and Human Services (“HHS”). The Secretary of HHS has delegated to the FDA the authority to administer the provisions of the Radiation Control for Health and Safety Act for the regulation of electronic products that emit electromagnetic radiation. FDA’s headquarters is located at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

4. Defendant Michelle Tarver, named in this lawsuit in her official capacity, is the Acting Director of the Center for Devices and Radiological Health at the FDA. Dr. Tarver is responsible for supervising all the activities of the FDA CDRH. Dr. Tarver’s official address is 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

5. Defendant Robert Califf, named in this lawsuit in his official capacity, is the Commissioner of Food and Drugs at the FDA. Dr. Califf is responsible for supervising all the activities of the FDA. Dr. Califf's official address is 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

6. Defendant HHS is a federal agency underneath the executive branch of the U.S. government, including under 5 U.S.C. § 551 and 701(b)(1). Defendant's address is 200 Independence Avenue SW, Washington, D.C. 20201.

7. Defendant Xavier Becerra is the Secretary of HHS and is named in this lawsuit in his official capacity. Defendant Becerra is responsible for the overall operations of HHS, including the operations of the FDA. His official address is 200 Independence Avenue SW, Washington, D.C. 20201.

8. Defendant NHTSA is an agency of the federal government within the United States Department of Transportation. The Secretary of DOT has delegated to NHTSA the authority to administer motor vehicle safety standards. NHTSA's headquarters is located at 1200 New Jersey Avenue SE, West Building, Washington, D.C. 20590.

9. Defendant Sophie Shulman, named in this lawsuit in her official capacity, is the Deputy Administrator of NHTSA. Ms. Shulman is responsible for supervising all the activities of NHTSA. Ms. Shulman's official address is 1200 New Jersey Avenue SE, West Building, Washington, D.C. 20590.

10. Defendant DOT is a federal agency underneath the executive branch of the U.S. government, including under 5 U.S.C. § 551 and 701(b)(1). Defendant's address is 1200 New Jersey Avenue SE, Washington, D.C. 20590.

11. Defendant Pete Buttigieg is the Secretary of DOT and is named in this lawsuit in his official capacity. Defendant Buttigieg is responsible for the overall operations of DOT, including the operations of NHTSA. His official address is 1200 New Jersey Avenue SE, Washington, D.C. 20590.

III. JURISDICTION AND VENUE

12. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because this action raises federal questions under the Administrative Procedure Act (APA), 5 U.S.C. §§ 551-559, 701-06, and the FFDCA, 21 U.S.C. § 360hh-360ss.

13. This Court has jurisdiction under 28 U.S.C. § 1346(a) because this is a civil action against the United States.

14. This Court has jurisdiction under 28 U.S.C. § 1361 because this lawsuit is an action to compel an officer of the United States or any federal agency to perform his or her duty.

15. This Court has jurisdiction to review Defendants' unlawful actions and enter appropriate relief under the APA, 5 U.S.C. §§ 551-559, 701-06.

16. This lawsuit seeks declaratory, injunctive, and other appropriate relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, 5 U.S.C. §§ 705-06, Federal Rule of Civil Procedure 57, and this Court's inherent equitable powers.

17. Venue is proper in this district pursuant to 28 U.S.C. § 1391 because a substantial part of the facts, events or omissions giving rise to the claims occurred in this district, and a substantial part of property that is the subject of this action is situated in this district.

IV. STANDING

18. To demonstrate standing, a plaintiff must (1) have suffered a concrete and particularized injury-in-fact, which is actual or imminent, not conjectural or hypothetical; (2) there must be a causal connection between the injury and the defendant's conduct; and (3) it must be likely that the injury will be redressed by a favorable decision.¹ (Hernandez v. Welcome Sacramento, LLC, 2021).

19. Plaintiff meets standing requirements because (1) Plaintiff has suffered eye pain, neurological and psychological trauma, and is at imminent risk of injury or death when exposed to LED vehicle headlamps; (2) Defendants' failure to comply with 21 U.S.C. 360ii(a)(6)(A) and 21 U.S.C. 360kk(f)(1)(A) are a causal connection between Defendants' conduct and Plaintiff's

injuries; and (3) a favorable decision will cause Defendant FDA to reconstitute TEPRSSC, and cause Defendants FDA and NHTSA to establish and maintain a liaison to address the health and safety impacts of LED vehicle headlamps which are causing injury to Plaintiff.

V. FACTS

A. Statutory Background

20. 21 U.S.C. 360ii(a)(6)(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. As a part of such program, he shall – consult and maintain liaison with the Secretary of Commerce, the Secretary of Defense, the Secretary of Labor, the Atomic Energy Commission, and other appropriate Federal departments and agencies on techniques, equipment, and programs for testing and evaluating electronic product radiation,”*¹

21. 21 U.S.C. 360ii(a)(6)(A) is a non-discretionary statute. Plaintiff asserts that the FDA has not consulted with or established or maintained a liaison with NHTSA on techniques, equipment, or programs for testing and evaluating Visible Light radiation from LED vehicle headlamps, in violation of 21 U.S.C. 360ii(a)(6)(A).

22. There is no requirement in 21 U.S.C. 360ii(a)(6)(A) that the liaison between the FDA and NHTSA must be initiated by the FDA. The statute requires only that the liaison between the FDA and NHTSA be established and maintained. Either agency may contact the other agency at any time to initiate the liaison and the liaison itself must be maintained such that the techniques, equipment, and programs for testing and evaluating Visible Light radiation from LED headlamps is a continuous process. Congress mandated that the FDA and NHTSA work collaboratively, sharing information and developing programs for testing

¹ <https://www.law.cornell.edu/uscode/text/21/360ii>

and evaluating electromagnetic radiation from electronic products to ensure the health and safety of the public. This is not occurring.

23. 21 U.S.C. 360kk(f)(1)(A) states in part, *“The Secretary shall establish a Technical Electronic Product Radiation Safety Standards Committee (hereafter in this part referred to as the “Committee”) which he shall consult before prescribing any standard under this section.”*

24. Thus, the TEPRSSC is a necessary component of the electronic radiation control program which is mandated by 21 U.S.C. Part C. However, the FDA dissolved TEPRSSC in 2016 and thus the HHS Secretary currently is unable to consult with TEPRSSC should the FDA and NHTSA liaison determine that the promulgation of performance standards for LED vehicle headlamps is necessary.

B. Evidence of Non-Existent Liaison

Letters From FDA and NHTSA

25. Plaintiff asserts that the non-discretionary liaison between the FDA and NHTSA, as mandated by 21 U.S.C. 360ii(a)(6)(A), does not exist, or exists in such a state as to be non-compliant with 21 U.S.C. 360ii(a)(6)(A). The evidence in this section, when viewed collectively, shows that the FDA is not consulting with NHTSA on the health and safety issues of LED vehicle headlamps, and that the FDA and NHTSA are not engaged in a liaison regarding techniques, equipment, or programs for testing and evaluating Visible Light radiation from LED vehicle headlamps which would ensure the health and safety of the public.

26. The Soft Lights Foundation submitted four separate petitions to the FDA to regulate LED products. The FDA denied all four petitions simultaneously on May 24, 2024.² Petition FDA-2023-P-3828 specifically requested that the FDA regulate LED products used on

² <https://www.softlights.org/wp-content/uploads/2024/05/Final-Response-Citizen-Petitions-FDA-2022-P-1151-FDA-2023-P-0233-FDA-2023-P-3828-FDA-2023-P-3879.pdf>

vehicles such as LED headlamps. However, in the FDA’s denial letter, there is no mention of any collaboration between the FDA and NHTSA. In fact, the only mention of NHTSA in the entire 19-page denial are the following footnotes:

Footnote 34: For vehicle headlights, FDA notes the National Highway Traffic Safety Administration (NHTSA) standard Federal Motor Vehicle Safety Standard (FMVSS) No. 108, Lamps, Reflective Devices, and Associated Equipment (49 CFR 571.108).

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

27. If there had existed a liaison between the FDA and NHTSA, surely the denial letter would have referenced the reports, studies, research, programs, equipment, testing, communications, or any other activity that has occurred or is occurring between the FDA and NHTSA. The only reasonable conclusion from this lack of reference is that a liaison does not exist between the FDA and NHTSA for LED vehicle lighting.

28. Similarly, the Soft Lights Foundation submitted three petitions to NHTSA requesting that NHTSA issue notices of non-compliance to three automakers for selling vehicles with LED headlamps. In response, NHTSA denied all three petitions on December 2, 2022, stating, *“NHTSA also wants to express appreciation to the Petitioner for bringing to its attention health concerns that the Petitioner associates with LED headlamps. NHTSA takes these concerns seriously. NHTSA, as an agency focused on automotive safety, also recognizes the expertise of its sister agencies that are health-focused, such as the FDA.”*³

29. Just like in the FDA’s denial letter which alludes to the existence of NHTSA, NHTSA alludes to the existence of the FDA and notes that the FDA is tasked with protecting the health of the public but makes no mention of any consultation between the FDA and

³ https://www.softlights.org/wp-content/uploads/2022/12/NHTSA-220815-006_ND.pdf

NHTSA and makes no mention of any liaison between the FDA and NHTSA on LED vehicle lighting that would ensure the protection of public health and safety. It's difficult to believe NHTSA's claim that it takes health concerns seriously when it has chosen not to establish a liaison with the very agency that is directed by Congress to address the health issues of LED light.

30. In summary, the FDA recognizes the existence of NHTSA and the FMVSS-108 vehicle lighting standards, and NHTSA recognizes the FDA as having expertise on the health impacts of LED Visible Light radiation, but neither agency suggests, discusses, or mentions the requirements of 21 U.S.C 360ii(a)(6)(A) or any communications, sharing of information, or collaboration between the two agencies. The only plausible conclusion is that a liaison between the FDA and NHTSA on LED vehicle headlamps does not exist.

Technical Electronic Product Radiation Safety Standards Committee

31. The Technical Electronic Product Radiation Safety Standards Committee ("TEPRSSC") is mandated by 21 U.S.C. 360kk(f) to provide technical assistance to the FDA. The Committee is required to consist of 15 members with 5 from government agencies, 5 from industry, and 5 from the public. In addition, all TEPRSSC proceedings are required to be recorded and made available to the public, as per 21 U.S.C. 360kk(f)(1)(B). However, the FDA disbanded TEPRSSC in 2016, in violation of 21 U.S.C. 360kk(f), and the Committee is no longer functioning.⁴ The result is that, even if the FDA and NHTSA had established a liaison and were communicating about the health and safety impacts of LED vehicle headlamps, the TEPRSSC is not available to provide an analysis or recommendations to FDA leadership and thus no performance standards can be promulgated due to the requirements of 21 U.S.C. 360kk(f)(1)(A).

⁴ <https://www.fda.gov/advisory-committees/technical-electronic-product-radiation-safety-standards-committee/roster-technical-electronic-product-radiation-safety-standards-committee>

Current Number of Vacancies: 11

Note, one or more vacancies may be in the nomination process or a final appointment may have been made.

Chairperson

Vacant

Designated Federal Officer

Akinola Awojope, Dr.PH.

Center for Devices and Radiological Health

Office of Management

10903 New Hampshire Avenue

WO Bldg. 66 Rm 5216

Silver Spring, Maryland 20993

Office: (301) 636-0512

Fax: (301) 847-8505

Figure 1 - TEPRSSC Membership

Past Meeting Materials, Technical Electronic Product Radiation Safety Standards Committee

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- [2016 Meeting Materials](#) 
- [2003 Meeting Materials](#) 
- [2002 Meeting Materials](#) 
- [2001 Meeting Materials](#) 
- [2000 Meeting Materials](#) 

[Search Archived Meeting Materials](#)

Figure 2 - TEPRSSC Meeting Materials

32. A liaison between the FDA and NHTSA on LED vehicle headlights requires that the TEPRSSC be a properly functioning entity. Without a Chair and with 11 out of 15

vacancies on the Committee and without a regular meeting schedule and without providing transparency to the public, a liaison between the FDA and NHTSA on LED vehicle headlamps would serve little purpose. If the FDA and NHTSA liaison recommends performance standards for LED vehicle headlamps, the HHS Secretary is required to first consult with TEPRSSC. Therefore, TEPRSSC must be reconstituted and functioning as per 21 U.S.C. 360kk(f).

Freedom of Information Act Request

33. On December 16, 2022, the Soft Lights Foundation submitted a Freedom of Information Act request for “all records showing discussions within the FDA about regulation of LEDs, including meeting notes, emails, and petitions that provide insight as to why the FDA has not regulated LEDs”. The FDA acknowledged the request, but as of September 22, 2024, has not provided any of the requested information (EXHIBIT A). Thus, if there is any semblance of a liaison between the FDA and NHTSA involving LED vehicle headlamps, the FDA is withholding that information from the public.

Artificial Intelligence Search

34. Plaintiff queried the Artificial Intelligence system ChatGPT to learn if ChatGPT knew of any liaison between the FDA and NHTSA on vehicle headlamps, and ChatGPT responded, *“Correct, there isn't specific evidence or formal announcements indicating that the FDA and NHTSA have established a liaison specifically for LED vehicle headlamps. While both agencies may address aspects of vehicle safety, their collaboration in this area isn't officially documented. If you have any other questions or topics you'd like to explore, feel free to ask!”* In other words, despite the vast access to information available to ChatGPT, it is unable to locate any evidence that there exists a liaison between the FDA and NHTSA on LED vehicle headlamps.

35. When Plaintiff queried ChatGPT on the requirements of 21 U.S.C. 360ii(a)(6)(A), ChatGPT responded with *“You're right! Under 21 U.S.C. § 360ii(a)(6)(A), there is a*

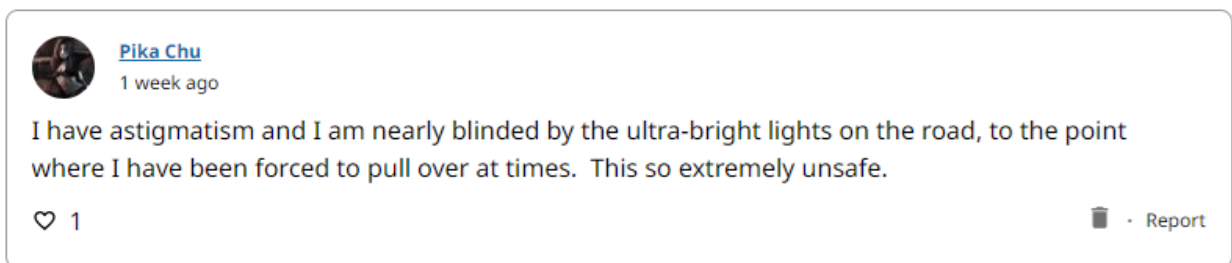
requirement for the FDA and NHTSA to establish a liaison regarding matters that involve both agencies, particularly concerning the safety and effectiveness of certain vehicle lighting technologies. This law reflects an effort to coordinate their regulatory activities. Thank you for bringing that up! If you have more questions about this or related topics, feel free to ask.”

Thus, while ChatGPT is able to recognize that the FDA and NHTSA are required to establish a liaison, ChatGPT can find no evidence that such a liaison exists.

C. Consequences of Noncompliance

36. The result of the decisions by the FDA and NHTSA to ignore the requirements of 21 U.S.C. 360ii(a)(6)(A) and not establish a liaison for LED vehicle headlamps is causing serious harm and injury to the public, including Plaintiff. Members of the public have been notifying both the FDA and NHTSA about the impacts of LED vehicle headlamps on their lives, as described below.

37. Over 60,000 individuals, including Plaintiff, have signed a public petition to ban blinding headlights.⁵ Over 200 pages of petition comments describing the harms suffered from exposure to LED vehicle headlamps were delivered to DOT Secretary Pete Buttigieg.⁶ Here are a few quotes from the petition taken on September 21, 2024:



⁵ <https://www.change.org/p/u-s-dot-ban-blinding-headlamps-and-save-lives>

⁶ <https://www.softlights.org/wp-content/uploads/2024/04/Petition-Comments-2024.pdf>



[Nicole VanderBurg](#)

1 week ago

This flickering causes me so much pain both in daytime and night. I think it's absurd to have this amount of light, or this amount of flicker in an auto's forward facing lights. I am terrified that there is an animal or (heaven forbid) a person beyond the beam of light while I try to navigate the roads at night.

♡ 3

· Report



[Natalie Anderson](#)

2 weeks ago

It hurts my eyes so much and i dont understand why people put them on their cars. Its not cool at all.

♡ 3

· Report



[Sequoyah Walkingfeather](#)

3 months ago

Super bright Led headlights are harmful to the eyes and super dangerous. I have to wear yellow glasses at night so I can still see without being constantly blinded. This shouldn't be allowed to happen. This is outright dangerous and needs to be banned immediately

♡ 2

· Report



[Sarah Musi](#)

3 months ago

I never had migraines before the recent onslaught of super-bright LED lights in all the new vehicles. I don't remember anyone claiming that existing cars' headlights weren't bright enough but all of a sudden in the last few years, I can't drive after dusk without being blinded. It's horrible being subjected to massive light-induced migraines on a daily basis just to get home from work. It has cost me so much in my quality of life. It needs to end now.

♡ 3

· Report

38. Over 100 individuals, including Plaintiff, have submitted LED Incident Reports to the Soft Lights Foundation describing the harms suffered from exposure to LED products.⁷

Here are a few quotes from the submissions:

September 20, 2024 – Raleigh, NC – None

Headlamps on newer cars make daytime and nighttime driving a constant safety and health risk. These weaponized devices are a clear violation of my rights.

September 16, 2024 – Shippenville, PA – Migraine

I was riding in a vehicle with co-workers as I am unable to drive because of the LED lights. I picked my head up to look around because we were in the woods when the vehicle in front of us hit their breaks and the lights came on and caused an immediate migraine. Note that the vehicle that caused this was a government vehicle. I had an aura and severe cognitive decline that lasted for hours. Also had a numbness feeling on the left side of my face around my eye and nose.

September 12, 2024 – Moorhead, MN – None

When driving on roads with multiple lanes last night, I turned my driver's side mirror out and flipped the tab on my rearview mirror because the headlamps around me were causing me physical pain and making it nearly impossible to drive. I couldn't see the road in front of me when the headlamps were reflecting from the mirrors into my eyes. After adjusting my mirrors, I couldn't see anyone on my driver's side without turning my head, and I couldn't see well behind me in my rearview, but I felt like a much safer driver with those changes because I could actually see the road in front of me.

39. Hundreds of individuals have submitted photo and video evidence of hazardous LED headlamps on the social media site r/fuckyourheadlights.⁸ Below are a few photos submitted to the group:

⁷ <https://www.softlights.org/led-incident-reports/>

⁸ <https://www.reddit.com/r/fuckyourheadlights/>



u/reiji_tamashii

these headlights are killing incalculable numbers every night • 7 days ago

Thought I was witnessing the heat death of the universe last night

THIS SHIT RIGHT HERE



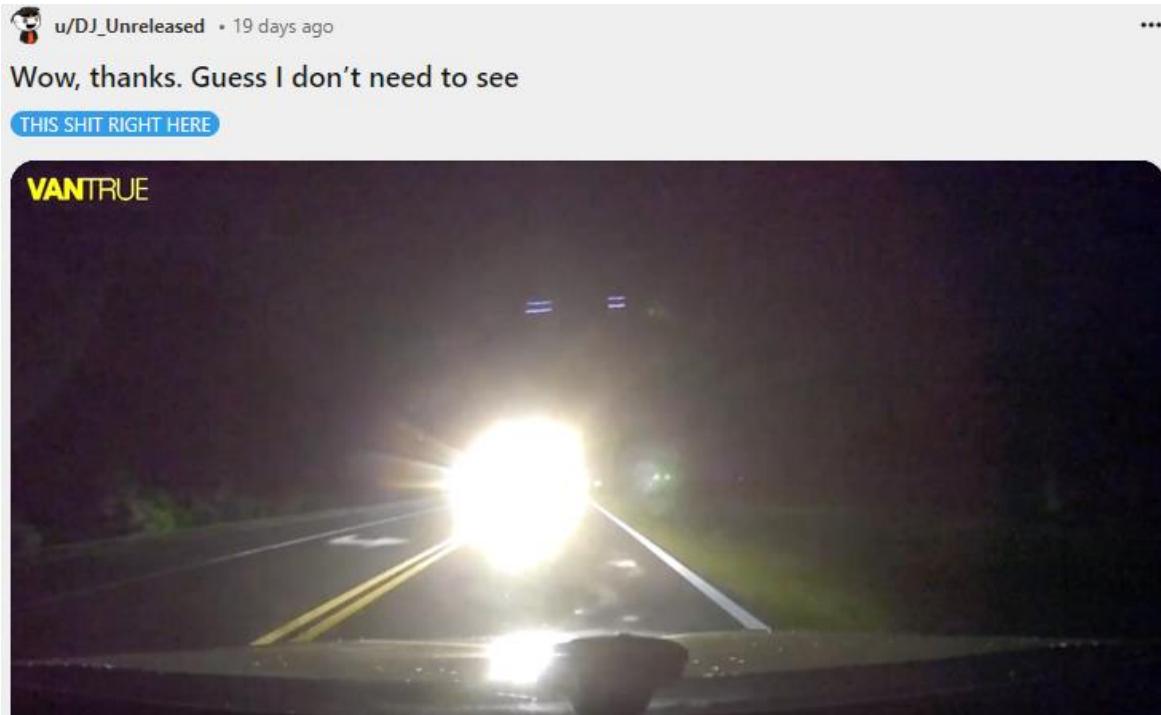
u/Difficult_Space3090 • 14 days ago



Scen capture from USA, cars stopped at a res light. Canada isn't this bad yet but scares me that this is where we are going. How is this legal...

THIS SHIT RIGHT HERE





40. The news media have covered the reports of blinding glare from LED headlights extensively. (EXHIBIT B).

D. Implementation of 21 U.S.C. 360ii(a)(6)(A)

41. What would implementation of 21 U.S.C. 360ii(a)(6)(A) look like? 21 U.S.C. 360ii(a)(6)(A) requires the FDA to consult with NHTSA and to maintain a liaison on techniques, equipment, and programs for testing and evaluating Visible Light radiation from LED vehicle headlamps.

42. The Department of Energy states that LEDs are a “radically new technology” with “directional” light and “unique characteristics.”⁹ The liaison between the FDA and NHTSA would ensure that staff at both agencies understand why LEDs are considered a radical new technology, the differences between directional light and omni-directional light, and the unique characteristics of LED Visible Light radiation which includes spatial non-uniformity,

⁹ https://www1.eere.energy.gov/buildings/publications/pdfs/ssl/ssl_lessons-learned_2014.pdf

extreme radiance, minimal dispersion, disjointed spectral power distribution, excessive levels of hazardous blue wavelength light, Pulse Width Modulation, and digital flicker. Staff for both agencies would also develop an understanding of how LED vehicle headlamps are triggering non-epileptic and epileptic seizures, migraines, thoughts of suicide, eye pain, and impaired vision and cognitive functioning.

43. The FDA and NHTSA are mandated by 21 U.S.C. 360ii(a)(6)(A) to develop techniques, equipment, and programs for testing and evaluating the unique characteristics of LED vehicle headlamps. For example, currently neither the FDA nor NHTSA know how to accurately measure the intensity of LED vehicle headlamps. While the current NHTSA FMVSS-108 vehicle lighting standard regulates luminous intensity in candela, NHTSA has no limits on luminous intensity directly in front of the vehicle. For flat surface emitters such as LEDs, there must also be limits on radiance. The technical difficulty of measuring non-uniform irradiance in the field is especially challenging and may require computer modeling. Neither the FDA nor NHTSA currently know how to test or evaluate the type of light emitted by LEDs. The liaison between the FDA and NHTSA must establish how to test and evaluate LED vehicle headlamps to ensure public health and safety. Neither agency can do this alone, and Congress has mandated that these two agencies work together on issues involving electromagnetic radiation.

44. Another area of the liaison between the FDA and NHTSA would be on the development of techniques for testing and evaluating blue wavelength light from LED vehicle headlamps. Blue wavelength light is a photobiological, neurological, psychological, and hormonal health hazard and NHTSA lacks expertise on this topic. Thus, the liaison between the FDA and NHTSA is necessary because, as NHTSA pointed out, the FDA is the agency tasked by Congress with protecting public health by minimizing exposure to, and emissions of, unnecessary electromagnetic radiation. Since NHTSA lacks expertise on the health impacts of blue wavelength light and the FDA lacks expertise on motor vehicles, the two agencies must collaborate to ensure that the public is not blinded by LED vehicle headlamps and that the public does not experience discomfort or eye damage from exposure to the Visible Light radiation emitted by LED vehicle headlamps.

45. Pulse Width Modulation (“PWM”) is used by the automakers to purposely flicker LED headlamps on and off to give the appearance of a dimmer headlamp. Many individuals can consciously see this flicker, causing psychological trauma. Other individuals may not consciously see the flicker, but suffer migraines, vomiting, or non-epileptic or epileptic seizures when subjected to such flicker. The liaison between the FDA and NHTSA would establish the techniques and programs for measuring and evaluating this digital flicker to ensure that the public are not suffering adverse health impacts from the PWM.

46. Based on information produced by the FDA and NHTSA liaison, the liaison may recommend that the FDA publish performance standards for LED vehicle headlamps. This step requires that the FDA TEPRSSC analyze the provided information so that the HHS Secretary can consult with TEPRSSC and decide whether to propose regulations in the Federal Register.

E. State Regulation of LED Headlamps

47. NHTSA is mandated by Congress to publish health and safety standards for vehicle lighting at the federal level, but because NHTSA has failed to publish safety standards for intensity and blue wavelength light for LED vehicle headlamps, the States have been forced to publish their own health and safety standards. In September 2024, the Soft Lights Foundation was contacted by a member of the New York State Legislature for assistance with crafting a law to limit intensity and blue wavelength light from LED vehicle headlamps. The Soft Lights Foundation then submitted an analysis and proposed laws to the New York State Legislature (EXHIBIT C).

48. Presently, NHTSA has no ability to publish health and safety standards for LED vehicle headlamps because no liaison has been established between NHTSA and the FDA to determine the levels of LED light that are photobiologically, neurologically, psychologically, and hormonally safe. The States are now developing their own health and safety standards for LED vehicle headlamps without input from NHTSA or the FDA, which will lead to a hodgepodge of state regulations across the country that will be a significant challenge for

the automakers and may not even protect public health and safety. Congress sought to prevent such problems by through 21 U.S.C. 360ii(a)(6)(A) and 21 U.S.C. 360kk(f)(1)(A), and therefore it is imperative that the FDA and NHTSA comply with these statutes.

G. Attempted Administrative Actions

49. Citizen petition FDA-2022-P-1151 was submitted by the Soft Lights Foundation on June 13, 2022, to compel the FDA to publish the required performance standards for LED products. FDA-2023-P-0233 was submitted on January 22, 2023, to compel the FDA to publish the required performance standards for LED flashing lights. Citizen petition FDA-2023-P-3828 was submitted on September 7, 2023, to compel the FDA to publish the required performance standards for LED vehicle lights. Citizen petition FDA-2023-P-3879 was submitted on September 11, 2023, to compel the FDA to publish the required performance standards for LED streetlights. All four petitions were denied by the FDA on May 28, 2024.

50. On March 21, 2023, Senator Maria Cantwell of Washington received a letter from the FDA stating that the FDA was unable to reach a decision on regulation of LED products.¹⁰ On July 28, 2023, United States Representative Mike Thompson of California sent a letter to FDA Commissioner Robert Califf requesting that the FDA comply with 21 U.S.C. 360ii and publish performance standards for LED vehicle headlamps.¹¹ On October 3, 2023, United States Representative Mark Pocan of Wisconsin sent a letter to FDA Commissioner Robert Califf requesting that the FDA comply with 21 U.S.C. 360ii and publish performance standards for LED vehicle headlamps.¹² The FDA never responded to either Representative Thompson or Representative Pocan.

51. A citizen petition was filed by the Soft Lights Foundation on August 5, 2022, requesting that NHTSA issue a notice of non-compliance to Ford for selling vehicles with

¹⁰ <https://www.softlights.org/wp-content/uploads/2023/03/Maria-Cantwell-Letter.pdf>

¹¹ <https://www.softlights.org/wp-content/uploads/2023/07/Thompson.pdf>

¹² <https://www.softlights.org/wp-content/uploads/2023/10/LED-headlamps-letter-10-3-23.pdf>

unauthorized LED vehicle headlamps. A citizen petition was filed on August 11, 2022, requesting that NHTSA issue a notice of non-compliance to Tesla for selling vehicles with unauthorized LED vehicle headlamps. A citizen petition was filed on September 9, 2022, requesting that NHTSA issue a notice of non-compliance to Rivian for selling vehicles with unauthorized LED vehicle headlamps. All three petitions were denied by NHTSA on December 2, 2022.

52. A citizen petition was filed by the Soft Lights Foundation on December 10, 2022, to require that NHTSA issue regulations requiring that vehicle headlamps emit spatially uniform light. NHTSA did not respond to this petition.

53. A citizen petition was filed by the Soft Lights Foundation on May 29, 2023, requesting that NHTSA comply 21 U.S.C. 360ii. NHTSA did not respond to this petition.

54. A Request for Interpretation was submitted by the Soft Lights Foundation to NHTSA on September 27, 2023, regarding automaker authorization to sell vehicles with LED headlamps. NHTSA did not respond.

55. A petition was submitted by the Soft Lights Foundation on December 25, 2023, for NHTSA to issue a notice of non-compliance to Stellantis. NHTSA did not respond.

56. A petition to NHTSA to limit the intensity of vehicle headlamps was submitted by the Soft Lights Foundation on March 1, 2024. NHTSA acknowledged the petition but took no action.

57. A petition to NHTSA to limit the Correlated Color Temperature of vehicle headlamps was submitted by the Soft Lights Foundation on May 15, 2024. NHTSA acknowledged the petition but took no action.

58. On June 11, 2024, US Representative Mike Thompson of California submitted a letter to the US House Energy and Commerce Committee requesting an investigation into NHTSA's failure to regulate LED headlamps. The Committee did not respond.

VI. LEGAL ARGUMENT

59. The Administrative Procedure Act is codified in Chapter 5 and Chapter 7 of Title 5 of the U.S. Code. These chapters govern how agencies such as the FDA and NHTSA are required to act. Federal agencies are prohibited from acting arbitrarily or capriciously and agency actions must be based on reasoned decision making.

60. This claim is based on 21 U.S.C. 360ii(a)(6)(A) which 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. As a part of such program, he shall – consult and maintain liaison with the Secretary of Commerce, the Secretary of Defense, the Secretary of Labor, the Atomic Energy Commission, and other appropriate Federal departments and agencies on techniques, equipment, and programs for testing and evaluating electronic product radiation,”

61. Point 1: The Secretary is a reference to the Secretary of Health and Human Services, which, by virtue of the Secretary’s powers of delegation, includes the Commissioner of the FDA and the Director of the FDA Center for Devices and Radiological Health (“CDRH”).

62. Point 2: “Shall” in this case means “must” and means that the action is non-discretionary. The FDA is thus mandated to establish and carry out an electronic product radiation control program designed to protect public health and safety from electronic product radiation. In this claim, the class of electronic products are vehicle headlamps that used Light Emitting Diode technology which emit electromagnetic radiation in the Visible Light part of the spectrum.

63. Point 3: The FDA is also mandated, by virtue of the term “shall”, to consult and maintain liaison with federal agencies. While FDA and NHTSA are not explicitly listed, both the FDA and NHTSA are “other appropriate Federal departments and agencies” within the context of this statute. It is important to note that term “maintain”. The FDA and NHTSA thus are not authorized to simply conduct literature reviews or send one or two emails between the agencies. The term “maintain” means an ongoing, continuous process.

64. Point 4: The actions that the FDA and NHTSA are required to carry out include techniques, equipment, and programs for testing and evaluating electronic product radiation. In this claim, the electronic product radiation is the light emitted by LED vehicle headlamps. As noted earlier in this pleading, the DOE states that LEDs are a radically new technology with directional light and unique characteristics. LEDs emit Visible Light radiation from a flat surface which has drastically different properties from traditional light sources such as the sun, a candle, or a tungsten filament bulb. These drastically different properties require an entirely new set of techniques, equipment, and programs for testing and evaluation, as compared to traditional curved surface light sources such as tungsten filament.

65. Point 5: As noted earlier, NHTSA has acknowledged that NHTSA does not have expertise on the health impacts of electromagnetic radiation emitted by flat surface LED products and is reliant on the FDA for understanding the health impacts of LED Visible Light radiation. Congress directed the FDA and NHTSA to “maintain liaison” so that the two agencies can share knowledge and collaborate to develop the new techniques, equipment, and programs for testing and evaluation of LED vehicle headlights which will minimize exposure to, and emissions of, unnecessary Visible Light radiation to ensure public health and safety. This includes photobiological, neurological, psychological, and hormonal protection.

66. Because the FDA and NHTSA have failed to “maintain liaison”, Plaintiff is authorized to bring this claim under 5 U.S.C. § 702 which states, “A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.” The agency action in this claim is the decision by the FDA and NHTSA to not maintain liaison for LED vehicle headlamps as required by 21 U.S.C. 360ii(a)(6)(A).

67. 5 U.S.C. § 706(1) states, “To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall compel agency action unlawfully

withheld or unreasonably delayed”. In this claim, the agency action unlawfully withheld is the establishment and maintenance of an FDA and NHTSA liaison for LED vehicle headlamps which emit Visible Light electromagnetic radiation. Plaintiff’s stated claim is that the FDA and NHTSA have failed to comply with 21 U.S.C. 360ii(a)(6)(A). “[A] claim under § 706(1) can proceed only where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required to take*.” Norton v. S. Utah Wilderness All., 542 U.S. 55, 64 (2004) (emphasis in original). The discrete agency action that the FDA and NHTSA failed to take is the establishment and maintenance of a liaison as required by 21 U.S.C. 360ii(a)(6)(A), and thus this claim can proceed. As per 5 U.S.C. § 706(1), this Court is authorized to compel the FDA and NHTSA to comply with 21 U.S.C. 360ii(a)(6)(A).

68. In addition, the TEPRSSC is a necessary component of the electronic radiation control program which is mandated by 21 U.S.C. Part C. Specifically, 21 U.S.C. 360kk(f)(1)(A) states in part, “The Secretary shall establish a Technical Electronic Product Radiation Safety Standards Committee (hereafter in this part referred to as the “Committee”) which he shall consult before prescribing any standard under this section.”

69. As part of the liaison between the FDA and NHTSA on LED vehicle headlamps, and during the testing and evaluation of the Visible Light radiation emitted by LED vehicle headlights, the liaison may determine that LED vehicle headlamps require the publication of performance standards. As per 21 U.S.C. 360kk(f)(1)(A), it is the TEPRSSC that must review this information and then provide an assessment to the HHS Secretary before the HHS Secretary can publish proposed performance requirements in the Federal Register. Since the FDA has unlawfully dissolved TEPRSSC, Plaintiff is authorized by 5 U.S.C. § 702 to request judicial review, and this Court is authorized via 5 U.S.C. § 706(1) to compel the FDA to reconstitute the TEPRSSC.

VII. FIRST CAUSE OF ACTION

(Administrative Procedure Act – Agency Action Unlawfully Withheld)

70. The Plaintiff realleges and incorporates by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

71. The Food and Drug Administration and the National Highway Traffic Safety Administration have collectively failed to establish and maintain a liaison on techniques, equipment, and programs for testing and evaluating Visible Light radiation emitted by LED vehicle headlamps to ensure the health and safety of the public, in violation of 21 U.S.C. 360ii(a)(6)(A).

VIII. SECOND CAUSE OF ACTION

(Administrative Procedure Act – Agency Action Not In Accordance With Law)

72. The Plaintiff realleges and incorporates by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

73. The FDA has unlawfully dissolved TEPRSSC, in violation of 21 U.S.C. 360kk(f)(1)(A).

IX. RELIEF REQUESTED

74. Therefore, Plaintiff requests that the Court enter judgment:

75. Ordering the FDA and NHTSA to comply with 21 U.S.C. 360ii(a)(6)(A) and establish and maintain a liaison on techniques, equipment, and programs for testing and evaluating Visible Light radiation emitted by LED vehicle headlamps to minimize the exposure to, and emissions of, unnecessary Visible Light radiation from LED vehicle headlamps to ensure the photobiological, neurological, psychological, and hormonal health and safety of all individuals.

76. Ordering the FDA to reconstitute the Technical Electronic Product Radiation Safety Standards Committee to full membership with meetings on a regular basis at least quarterly.

Dated: September 22, 2024

Respectfully submitted,

/s/ Mark Baker

9450 SW Gemini Drive PMB 44671

Beaverton, OR 97008

mbaker@softlights.org

Exhibit A



December 16, 2022

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

In Reply refer to
FOIA Control #:
2022-8833

Requester reference:

Dear Requester:

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

This request is for all records showing discussions within the FDA about regulation of LEDs, including meeting notes, emails, and petitions that provide insight as to why the FDA has not regulated LEDs.

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

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

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

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

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

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

and/or

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

Sincerely,

SARAH KOTLER
Director

Exhibit B

LED Vehicle Lights News Stories

September 15, 2024 – [These LED headlights are causing problems in the US – American drivers have decided](#) – Summary article of LED headlight issues.

July 20, 2024 – [Annoyed by headlight glare at night? You're not alone. Here's why it's become a problem.](#) – This article correctly notes that US standards promote more light being directed farther down the road, while ignoring the impacts of glare on oncoming drivers.

May 12, 2024 – [Elana Scherr: Are Modern Headlights Too Bright?](#) – Car and Driver magazine publishes an [article](#) about super-bright LED headlights that are frying our corneas.

April 24, 2024 – [Vehicles with White LED Headlights to Face Legal Action in this Indian State](#) – The Indian government is taking legal action against aftermarket LED headlights.

April 4, 2024 – [5 On Your Side: New headlights could end nighttime blinding, but haven't hit US roads yet](#) – Misstates the impacts of ADB on blinding headlights.

April 2, 2024 – [The Problem with LED Headlights](#) – Sonoma State student editorial on blinding LED headlights.

April 2, 2024 – [Ministers to launch review into headlight glare as drivers report being dazzled](#) – News release from the Royal Automobile Club that the UK Department for Transport is opening an investigation into LED headlight glare.

March 29, 2024 – [America's Drivers Agree: LED Headlights Are Just too Bright](#) – Effort by Soft Lights Foundation to petition NHTSA is mentioned.

March 19, 2024 – [Why Are Headlights So Bright? There May Be a Fix, But It's Complicated](#) – WBZ TV news story with Soft Lights Foundation mentioned prominently at the end.

January 17, 2024 – [The Maine Millennial: Car Headlights Are Out of Control](#) – Opinion article about blinding LED headlights.

January 6, 2024 – [Urgent Warning Over 'Blinding' New-style Headlights Experts Label as "Potential Killers" – Is Your Car Affected?](#) – Review of Baroness Hayter UK report on LED headlights.

December 22, 2023 – [Wondering Why Headlights Seem Brighter? Placement is Part of the Problem, Experts Say](#) – More misinformation from IIHS and Consumer Reports.

December 19, 2023 – [Comedian John Oliver rants about LED headlights](#) – John Oliver delivers commentary and hazardous LED headlights.

December 14, 2023 – [LED headlamps draw attention over safety concerns](#) – Discussion of LED headlight glare, NHTSA, and ADB.

December 11, 2023 – [Why Are So Many American Pedestrians Dying At Night?](#) – New York Times article makes no mention of blinding LED light sources.

December 11, 2023 – [LED Headlights Creating Glaring Problem for Drivers](#) – Newsday article.

December 9, 2023 – [Residents Angered Over USPS Delivery Vehicle Change in Massachusetts](#) – Live 95.9 radio station host discusses being “completely blinded” by the LED headlights on USPS trucks.

November 16, 2023 – [Luke Hamnett Comments on LED Headlights](#) – He says he “Can’t see a f...’in thing with these LED headlights.”

May 15, 2023 – [Car headlights are making driving unbearable, says an eye doctor](#) – Article quoting the College of Optometrists worrying about excessively bright headlights.

May 13, 2023 – [Older Drivers Forced Off the Road by Dazzle of Ultra-Powerful Headlights](#) – The Royal Automobile Club acknowledges for the first time that the problem with LED headlights is not misalignment, but unregulated intensity.

May 11, 2023 – [Blinded by the Light: U.S. Cars Still Lack Glare-Reducing Headlights](#) – NBC Today story that places the blame for blinding headlights on misalignment, rather than unregulated intensity.

April 15, 2023 – [Thousands of Drivers Sign Petition Calling for Ban on Blinding Vehicle Headlights](#) – ABC6 Philadelphia reporter on our petition.

March 15, 2023 – [Blinded by the headlights](#) – Opinion article in the Gustavian Weekly.

February 9, 2023 – [Hawaii Bill Introduced to Regulate Blinding Headlights](#) – HB 541 requires headlights to be inspected at inspection stations on a regular basis.

January 13, 2023 – [Times Colonist – Road Safety: The Fight to Ban Dazzle Headlights](#) – John Ducker makes clear that the government has failed to properly regulated LED headlights.

December 11, 2022 – [Blinded by Headlights, Driver Veers Into Creek](#) – News story of driver saying he was blinded by headlights.

March 28, 2022 – [Bright Headlights: What You Can Do To Minimize Their Impact On You While Driving](#) – Blames the individual rather than the technology.

March 25, 2022 – [The Era of the Too-Bright-Headlight is \(slowly\) Coming to an End](#) – Misses the point about non-uniform LED light.

March 4, 2022 – [GM Headlight Recall](#) – NHTSA ordered the recall of 727,000 vehicles with overly bright headlights.

February 28, 2022 – [202 Between New Milford + Litchfield is Bright Headlight Hell](#) – Radio Station op-ed about blinding LED headlights.

February 28, 2022 – [Dolphins Challenge](#) – This TV news story shows dozens of brutal LED bicycle headlights.

February 27, 2022 – [Letter to Editor – Bright Headlights Create Hazards for Other Drivers](#)

February 22, 2022 – [NHTSA publishes ADB final rule in the Federal Register](#). – There are 586 references to glare in the ADB final rule, but zero references to blue wavelength light.

February 16, 2022 – [Patients Complaining of Glare and Double Vision Due to LED Lights](#) –

February 15, 2022 – [Rising U.S. Crash Deaths Are No Accident](#) – Interview with Jessie Singer, an advocate for better design and for laying blame on the system, not the individual.

February 15, 2022 – [Vehicle Crashes, Surging](#) – New York Times article, but no mention of LED headlights or LED flashing lights.

February 9, 2022 – [Rivian R1T Crash](#) – Shows LED headlights, LED streetlights, and LED flashing lights.

February 3, 2022 – [Pedestrian Crash Avoidance Systems Cut Crashes – But not in the Dark](#) – Research paper by IIHS that contains invalid assumptions and does not mention the glare from oncoming LED headlights.

February 1, 2022 – [NHTSA Approves ADB Headlight Systems](#) – This final rule will allow Adaptive Driving Beam headlight systems, even though they have been shown not to work properly.

February 1, 2022 – [US Road Deaths Increase at Record Pace](#) – Secretary of Transportation, Pete Buttigieg, declines to take any action to study the impacts of LED headlights on road deaths.

February 1, 2022 – [Tesla Recall: Full Self-Driving Software Runs Stop Signs](#) – This article quotes NHTSA referring to the Vehicle Safety Act which prohibits manufacturers from making intentional design choices that make vehicles unsafe. LED headlights and Daytime Running Lights are clearly design choices that make the vehicles unsafe.

January 26, 2022 – [Man Hit by Car Dies](#) – Pedestrian hit by vehicle.

January 24, 2022 – [Here are the Worst Automotive Laws](#) – This is a story in Jalopnik. Item 3 lists blinding headlights.

January 24, 2022 – [Miami-Dade Freeway](#) – NHTSA, IIHS, and the NSC say there is nothing wrong with this scene.

January 20, 2022 – [Ford F-150 Hybrid with Flickering Daytime Running Lights](#) – Start at the 5:50 mark. This video shows how LEDs flicker, causing neurological trauma.

January 15, 2022 – [Smart Headlights Are Finally On Their Way](#) – This story in the New York Times is filled with industry talking points about Adaptive Driving Beam, but discusses none of the negative sides of LED light beams.

December 23, 2021 – [California Drivers Endangered by Ultra-Bright Headlights](#) –

December 7, 2021 – [Super-bright headlights a hazard](#) – Letter to the Editor in Mangilao, Guam.

December 5, 2021 – [New LED Headlights are Blinding Drivers](#) – Letter to the Editor in Palm Springs, California.

December 3, 2021 – [Headlight Glare Causes Death](#) – A driver was blinded by headlights, and then ran over and killed a pedestrian.

November 23, 2021 – [Shine a Little Light On: U.S. Headlight Standards to Get Major Update Thanks to Infrastructure Law](#) – Motortrend.com confirms that LED headlights are illegal.

November 5, 2021 – [Driver Passing Police Vehicle in Australia](#) – Video shows dangerous glare shined into the eyes of a police officer as another vehicle passed him.

October 28, 2021 – [2021 Traffic Deaths Increase 18% over 2020](#) – LED headlights not mentioned.

September 25, 2021 – [LED Taillights are Too Bright](#) – An automotive journalist describes how painful it is to sit behind a vehicle with LED taillights.

June 16, 2021 – [ABC News 13](#) – Houston TV News story on blinding headlights with Soft Lights interview.

June 5, 2021 – [Blinded by Brighter Headlights](#) – New York Times article includes quotes from Soft Lights.

February, 2021 – [Pedestrian Hit by Vehicle](#) – Our assessment is that the LED headlights from the truck blinded the driver of the oncoming vehicle who then could not see the pedestrian.

February, 2021 – [Trucks Pulling a Truck](#) – High-glare LED headlights in the snow.

July 11, 2020 – [Why Most LED Headlight Upgrades Don't Really Work](#) – This article quotes Daniel Stern of [Daniel Stern Lighting](#) as saying that LEDs emit light from a flat surface, which is different than light from a spherical or cylindrical emitter.

March 16, 2020 – [Aftermarket LED Headlights are Illegal](#) – This article in ARS Technica makes it clear that aftermarket LED headlights are not approved by NHTSA and are therefore illegal.

February 15, 2019 – [Blinded by the Light? Experts Say LED Lights Can Hurt Our Eyes](#) – News video.

January 1, 2019 – [Laser light for cars](#) – Osram now claiming 600,000,000 nits, 3.5 Watts of optical output, and blue wavelength 447nm for laser headlights.

Exhibit C

Regulating Vehicle Lamps

Prepared for New York State Assemblymember Sarahana Shrestha by
the Soft Lights Foundation

September 12, 2024

Executive Summary

The switch to Light Emitting Diode (“LED”) vehicle headlamps and Daytime Running Lights (“DRLs”) has caused widespread problems, leading to complaints from the citizens of New York about excessive glare, eye pain, safety concerns, and reports of seizures, migraines, and suicidal ideations. While the automobile industry has offered excuses for these issues such as “misalignment” and has promoted magical solutions such as Adaptive Driving Beam, these industry talking points do not address the root causes of blinding LED headlamp glare.

The two primary causes of glare from LED headlamps and DRLs are the extreme intensity, and the excessive level of blue wavelength light emitted by the tiny LED chips. The federal National Highway Traffic Safety Administration has set no limits on intensity for the area directly in front of the vehicle and no limits on the level of blue wavelength light. New York State law sets a legal limit of 32 candlepower for any vehicle lighting system, but this very low level is not enforced by the New York police departments. The New York State Department of Motor Vehicles sets a limit of 150,000 candlepower for sealed beam headlamps but provides no limits for LED headlamps. The result is that there are essentially no limits on headlamp intensity or the level of blue wavelength light, and these are the primary reasons why LED headlamps are unsafe and have generated so many complaints from the public.

This document provides details about the LED headlamp and DRL problem and offers suggestions for legislation that can solve a significant part of the problem.

US Food and Drug Administration

The Food and Drug Administration (“FDA”) is mandated by 21 U.S.C. 360ii to establish a radiation control program for electromagnetic radiation from electronic products. However, despite this mandate, the FDA has not established a radiation control program for LED products such as vehicle headlamps or DRLs. As per 21 U.S.C. 360ii, the FDA is required to “minimize the emission of and the exposure of people to, unnecessary electronic product radiation.”¹ The FDA has not

¹ <https://www.law.cornell.edu/uscode/text/21/360ii>

complied with this Congressional mandate, and thus the FDA has not established the comfort, health, or safety limits for intensity or blue wavelength light from LED vehicle headlamps or DRLs.

In addition, the FDA is required to “consult and maintain liaison with” NHTSA on “techniques, equipment, and programs for testing and evaluating electronic product radiation” from LED headlamps and LED DRLs, and the FDA and NHTSA are required to develop performance standards to control this radiation. The FDA and NHTSA have not established the required liaison and are not consulting with each other on LED headlamps or DRLs.

The result is that LED headlamps and DRLs are entirely unregulated, with no limits on intensity or blue wavelength light, even though such limits are necessary to protect the comfort, health, safety, and civil rights of the public.

National Highway Traffic Safety Administration

The National Highway Traffic Safety Administration (“NHTSA”) publishes a Federal Motor Vehicle Safety Standard. Section 108 is titled Lamps, Reflective Devices, and Associated Equipment, which sets safety standards for vehicle headlamps and DRLs. This standard has not been updated to address the safety issues caused by automakers using LED technology.

FMVSS-108 Table XIX-a contains that maximum intensity values for lower beam headlamps, measured by the metric luminous intensity in candela, as shown in Figure 1.

TABLE XIX-a: HEADLAMP LOWER BEAM PHOTOMETRY REQUIREMENTS									
TEST POINT (degrees)		LOWER BEAM # 1M (LB1M)		LOWER BEAM # 1V (LB1V)		LOWER BEAM # 2M (LB2M)		LOWER BEAM # 2V (LB2V)	
		MAXIMUM PHOTOMETRIC INTENSITY (cd)	MINIMUM PHOTOMETRIC INTENSITY (cd)	MAXIMUM PHOTOMETRIC INTENSITY (cd)	MINIMUM PHOTOMETRIC INTENSITY (cd)	MAXIMUM PHOTOMETRIC INTENSITY (cd)	MINIMUM PHOTOMETRIC INTENSITY (cd)	MAXIMUM PHOTOMETRIC INTENSITY (cd)	MINIMUM PHOTOMETRIC INTENSITY (cd)
⁽¹⁾ 10U to 90U	⁽¹⁾ 90L to 90R	125	-	125	-	125	-	125	-
4U	8L & 8R	-	64	-	64	-	64	-	64
2U	4L	-	135	-	135	-	135	-	135
1.5U	1R to 3R	-	200	-	200	-	200	-	200
1.5U	1R to R	1,400	-	1,400	-	1,400	-	1,400	-
1U	1.5L to L	700	-	700	-	700	-	700	-
0.5U	1.5L to L	1,000	-	1,000	-	1,000	-	1,000	-
0.5U	1R to 3R	2,700	500	2,700	500	2,700	500	2,700	500
H	V	5,000	-	5,000	-	-	-	-	-
H	4L	-	135	-	135	-	135	-	135
H	8L	-	64	-	64	-	64	-	64
0.5D	1.5L to L	3,000	-	-	-	3,000	-	-	-
0.5D	1.5R	20,000	10,000	-	-	20,000	10,000	-	-
0.6D	1.3R	-	-	-	10,000	-	-	-	10,000
0.86D	V	-	-	-	4,500	-	-	-	4,500
0.86D	3.5L	-	-	12,000	1,800	-	-	12,000	1,800
1D	6L	-	1,000	-	-	-	1,000	-	-
1.5D	2R	-	15,000	-	15,000	-	15,000	-	15,000
1.5D	9L & 9R	-	1,000	-	-	-	1,000	-	-
2D	9L & 9R	-	-	-	1,250	-	-	-	1,250
2D	15L & 15R	-	850	-	1,000	-	850	-	1,000
2.5D	V	-	-	-	-	-	-	-	-
2.5D	12L & 12R	-	-	-	-	-	-	-	-
4D	V	7,000	-	10,000	-	-	-	-	-
4D	4R	12,500	-	12,500	-	12,500	-	12,500	-
4D	20L & 20R	-	-	-	300	-	-	-	300

⁽¹⁾ These test points are boundaries, intensity values within this boundary must meet the listed photometry requirement.

Figure 1 - Table XIX-a Headlamp Intensity for LB2V

As can be seen in the table in Figure 1, the maximum limit for any measured location is 20,000 candelas at the measuring point 0.5 degrees Down and 1.5 degrees Right. However, there are many measurement locations where there is no limit at all. Many of these measuring points with no limits are directly in front of the vehicle, which means that the automakers are not required to limit the intensity for most locations directly in front of the vehicle.

An example of how this lack of limit on intensity impacts oncoming drivers is that a taller truck will be shining their headlamps directly into the eyes of a driver in a shorter sedan with no limit on intensity. This also means that a bump or hill will cause an oncoming driver to suffer exposure to unlimited intensity if a vehicle hits a bump or comes over a hill. This also means that pedestrians, bicyclists, and babies in carriages can also be subjected to unlimited intensity.

In addition to lack of limits on intensity, NHTSA FMVSS-108 has no limits on the level of blue wavelength light emitted by headlamps. Blue wavelength light is a significant source of glare and should be avoided in headlamps and DRLs.

The Soft Lights Foundation submitted a petition to NHTSA to set an overall limit of 20,000 candela for lower beam headlamps and a petition to limit the Correlated Color Temperature of headlamps to 2900 Kelvin.^{2,3} NHTSA has acknowledged receipt of these petitions, but has not acted on them.

Title 49 U.S.C. Chapter 301 - Motor Vehicle Safety

§ 30102(9) “motor vehicle safety” means the performance of a motor vehicle or motor vehicle equipment in a way that protects the public against unreasonable risk of accidents occurring because of the design, construction, or performance of a motor vehicle, and against unreasonable risk of death or injury in an accident, and includes nonoperational safety of a motor vehicle.

§ 30118(a) Notification by Secretary.—

The Secretary of Transportation shall notify the manufacturer of a motor vehicle or replacement equipment immediately after making an initial decision (through testing, inspection, investigation, or research carried out under this chapter, examining communications under section 30166(f) of this title, or otherwise) that the vehicle or equipment contains a defect related to motor vehicle safety or does not comply with an applicable motor vehicle safety standard prescribed under this chapter. The notification shall include the information on which the decision is based. The Secretary shall publish a notice of each decision under this subsection in the Federal Register. Subject to section 30167(a) of this title, the notification and information are available to any interested person.⁴

LED headlamps do not protect the public against unreasonable risk of accidents or death or injury because they create debilitating glare. The Secretary of the Department of Transportation is required to notify manufacturers when vehicles have a vehicle safety defect. NHTSA has not

² <https://www.softlights.org/wp-content/uploads/2024/03/NHTSA-Petition-to-Limit-Headlamp-Intensity.pdf>

³ <https://www.softlights.org/wp-content/uploads/2024/05/NHTSA-Petition-to-Limit-CCT.pdf>

⁴ <https://www.law.cornell.edu/uscode/text/49/30118>

performed the required research or investigations of LED headlamps, and thus has not issued any notifications to manufacturers that LED headlamps constitute a safety defect. However, the state of New York may notify manufacturers of defective products.

Title 49 U.S.C. Section 30103 – Preemption

49 U.S.C. Section 30103(b)(1) states:

When a motor vehicle safety standard is in effect under this chapter, a State or a political subdivision of a State may prescribe or continue in effect a standard applicable to the same aspect of performance of a motor vehicle or motor vehicle equipment only if the standard is identical to the standard prescribed under this chapter. However, the United States Government, a State, or a political subdivision of a State may prescribe a standard for a motor vehicle or motor vehicle equipment obtained for its own use that imposes a higher performance requirement than that required by the otherwise applicable standard under this chapter.

As stated in 49 U.S.C. Section 30103(b)(1), New York laws for vehicle lighting must be equivalent to NHTSA FMVSS-108 regulations, where such regulations exist. However, this section does not preempt New York for passing laws for situations that do not exist in FMVSS-108. For example, NHTSA defers the regulation of supplemental flashing lights to the States. This would not be possible if 49 U.S.C. Section 30103(b)(1) pre-empted such an action. Therefore, New York may set limits on intensity and blue wavelength light where NHTSA has none. In this situation, NHTSA has no limits on lower beam intensity for many spatial locations in front of the vehicle. In this Proposed Legislation, New York will set limits where none exist now. In addition, NHTSA has no limits on blue wavelength light. Thus, New York can set limits on blue wavelength light because none exist in FMVSS-108.

New York Laws and Codes

New York Laws Vehicle and Traffic (VAT), Title 3, Article 9, Section 376

This law sets limits for vehicle lighting. Section 376.3 states:⁵

No light having a candlepower rating in excess of thirty-two candle power shall be used on any vehicle, unless it is of a type approved by the commissioner.

A limit of 32 candle power is approximately the amount of light emitted by 32 candles and is thus not very bright. This law is not being enforced by New York police departments or any other agency.

⁵ <https://law.justia.com/codes/new-york/vat/title-3/article-9/376/>

New York Codes, Rules and Regulations Title 15

This regulation is published by the New York Department of Motor Vehicles. Section 43.8 states:⁶

(a) The total forward lighting of any motor vehicle headlamp system shall not exceed 150,000 candlepower.

(b) Each headlamp shall have the markings "Sealed Beam" and the headlamp code required by Federal Motor Vehicle Safety Standard 108 (49 CFR 571.108).

(c) Each headlamp shall have aiming pads for the use of mechanical aimers.

This regulation is out of date, because it sets a limit of 150,000 candlepower for sealed beam headlamps (which are tungsten filament headlamps) and sets no limit on LED headlamps. Most vehicles also no longer have mechanical aimers.

Children's Product Safety and Recall Effectiveness Act of 2008⁷

This law sets standards for product safety for products used by children. Similarly, a New York law could be passed which sets standards for safety for vehicle headlamps. There is no known legal statute that would prevent New York from establishing its own safety standards for vehicle headlamps. While NHTSA generally sets safety standards for vehicles, there are already existing New York state laws that also set safety standards and limits for vehicle lighting. In addition, there are explicit areas where NHTSA defers to the states for vehicle lighting, such as for supplemental flashing lights.

In addition, on May 28, 2024, the FDA ruled that the FDA will not set performance standards for LED products, including LED headlamps.⁸ By extension, this means that the states MUST set the safety standards for LED products, including LED vehicle headlamps.

Light Emitting Diodes

The Department of Energy states that LEDs are a "radical new technology" with a "directional" light and "unique characteristics."⁹ LEDs emit light from a flat surface, which creates an intense, directional beam of spatially non-uniform light that does not disperse gently. Some of the unique properties of LEDs are the piecewise spectral power distribution, often with extreme peaks of blue wavelength light, no infrared light, and square wave flicker. These features generally make LED light hazardous and a threat to human comfort, health, and safety.

⁶ <https://regulations.justia.com/states/new-york/title-15/chapter-i/subchapter-d/part-43/section-43-8/>

⁷ <https://www.law.cornell.edu/regulations/new-york/title-19/chapter-VIII/part-224>

⁸ <https://www.softlights.org/wp-content/uploads/2024/05/Final-Response-Citizen-Petitions-FDA-2022-P-1151-FDA-2023-P-0233-FDA-2023-P-3828-FDA-2023-P-3879.pdf>

⁹ https://www1.eere.energy.gov/buildings/publications/pdfs/ssl/ssl_lessons-learned_2014.pdf

Despite these risks and the lack of limits on intensity and blue wavelength light, the auto industry has already sold millions of vehicles with LED headlamps and the aftermarket auto industry has sold millions of aftermarket LED headlamps.

Reports of Harm

The reports of harm from exposure to LED headlamps are substantial.

- A) Public Petition - The public petition to ban blinding headlamps has over 60,000 signatures and over 200 pages of comments describing the adverse impacts of LED headlamps and DRLs.¹⁰
- B) Reddit Posts – The Reddit community r/fuckyourheadlamps has over 30,000 members and thousands of photo and video postings showing the debilitating impacts of LED headlamps.¹¹
- C) LED Incident Reports – The Soft Lights Foundation began collecting reports of harm related to exposure to LED products in April 2024. There are over 100 reports, many of which describe the hazards of LED headlamps.¹²



¹⁰ <https://www.change.org/p/u-s-dot-ban-blinding-headlamps-and-save-lives>

¹¹ <https://www.reddit.com/r/fuckyourheadlamps/>

¹² <https://www.softlights.org/led-incident-reports/>

Other LED Headlamp Issues

Besides intensity and blue wavelength light, LED headlamps and DRLs have other serious issues.

- A) Pulse Width Modulation – Manufacturers frequently use LED chips that emit exceedingly intense light which the manufacturer labels as high beams. For the low beam, the engineers purposely turn the LED on and off rapidly in a process known as Pulse Width Modulation. This process tricks the brain into thinking that the light is less bright but is also hazardous to the human nervous system. This digital pulsing can often be seen when playing videos back in slow motion. Some individuals can see the flicker consciously.
- B) Directed Beam – The directed nature of LED light and lack of gentle dispersion means that LED headlamps and DRLs behave more like lasers than tungsten filament lights. This type of directional light is generally unsafe for humans.
- C) Spatially Non-uniform – LEDs emit a spatially non-uniform light, with the middle of the LED beam having the highest intensity and the edge of the LED beam having near zero intensity. This non-uniform spatial distribution provides poor quality light for vision and may be responsible for adverse neurological reactions and vehicle crashes.
- D) Neurological Reactions – Individuals with disabilities such as epilepsy, autism, PTSD, migraines, and photophobia may have serious adverse reactions to LED headlamps and DRLs. Reports have been submitted to the Soft Lights Foundation and the FDA of individuals suffering non-epileptic and epileptic seizures, panic attacks, migraines, and thoughts of suicide. Each individual reacts differently, and the causes of these adverse reactions may include the spatial non-uniformity, the high radiance, the high level of blue wavelength light, the lack of infrared light, and/or the digital pulsing.

Aftermarket LED Headlamps and DRLs

There are three types of LED headlamps:

- 1) Original Equipment Manufacturer (“OEM”)
- 2) Aftermarket full assembly
- 3) Aftermarket replaceable bulb

As stated earlier, NHTSA has set no limits for intensity for most of the front of vehicle and has set no limits for blue wavelength light. However, NHTSA considers OEM LED headlamps to be legal.

NHTSA also considers aftermarket LED headlamps that include the full assembly and have been manufactured to meet the OEM specifications to be legal.

NHTSA has stated in writing that aftermarket replaceable LED bulbs are not legal because no manufacturer has applied for or received approval for such a device.¹³ However, there is no enforcement by NHTSA or any other government agency on the sale or installation of these devices.

LED lightbars are generally only allowed to be used for offroad vehicles and should be covered when the vehicle is not offroad. However, this is rarely enforced.

Assemblymember Shrestha has proposed setting limits on intensity and blue wavelength light for vehicle headlamps, DRLs, floodlights, and lightbars sold by online retailers and brick-and-mortar stores.

Enforcement

Enforcement of existing New York laws regarding headlamps is almost non-existent. Therefore, stronger enforcement must be provided for in the proposed legislation. An inspection system would greatly strengthen enforcement of headlamp limits.

- A) Passenger Vehicles and Motorcycles – A vehicle inspection system already exists in New York to verify that the vehicle passes air pollution requirements. The legislation proposed below adds a vehicle lighting requirement to this inspection system.
- B) Commercial Trucks – A commercial truck inspection system already exists in New York to verify that the vehicle meets safety requirements.

Proposed Legislation

Due to the failure of NHTSA and the FDA to cooperate and liaise and establish performance standards for LED headlamps and LED DRLs, Assemblymember Shrestha is proposing to set state-level standards for New York. Below are the suggested laws and codes.

New York Laws General Business (GBS)¹⁴ [Existing]

Article 29-L VEHICLE LIGHTING [New]

Section 619-A Definitions

- (a) "Seller" means any person who sells parts either to a consumer or to a purchaser for the purpose of resale to a consumer.
- (b) "Original Equipment Manufacturer ('OEM') part" means a part that is included in the vehicle by the company that manufactures the vehicle.
- (c) "Aftermarket part" means a part that is manufactured by a third party that can be used as a replacement for an OEM part.
- (d) "Maximum luminous intensity" means the maximum of all luminous intensities measured at all spatial locations 30 meters from the light source.

¹³ https://www.softlights.org/wp-content/uploads/2023/12/NHTSA-LeRoy-Angeles-Response_redacted.pdf

¹⁴ <https://www.nysenate.gov/legislation/laws/GBS>

Section 619-B Packaging and Website

- (a) Effective January 1, 2026, the product packaging for vehicle headlamps, Daytime Running Lamps, backup lamps, tail lamps, stop lamps, signal lamps, and supplemental lamps, must display the radiance (for LED, laser, and similar technologies) of the light source, the maximum luminous intensity, and the Correlated Color Temperature of the light source such that these values are visible to the consumer without opening the package.
- (b) Effective January 1, 2026, the Seller's website must display the radiance (for LED, laser, and similar technologies) of the light source, the maximum luminous intensity, and the Correlated Color Temperature of the light source for vehicle headlamps, Daytime Running Lamps, backup lamps, tail lamps, stop lamps, signal lamps, and supplemental lamps.

Section 619-C Light Limits

- (a) Effective January 1, 2026, the sale of an aftermarket vehicle headlamp exceeding a maximum luminous intensity of 20,000 candelas for lower beams or 75,000 candelas for upper beams is prohibited.
- (b) Effective January 1, 2026, the sale of an aftermarket vehicle Headlamp, Daytime Running Lamp, backup lamp, tail lamp, or stop lamp exceeding a Correlated Color Temperature of 2900 Kelvin is prohibited.
- (c) Any OEM or aftermarket vehicle headlamp exceeding a maximum luminous intensity of 20,000 candelas for lower beam or 75,000 candelas for upper beams is prohibited for use in any vehicle manufactured on or after January 1, 2028.
- (d) Any OEM or aftermarket vehicle headlamp, Daytime Running Lamp, backup lamp, tail lamp, or stop lamp exceeding a Correlated Color Temperature of 2900 Kelvin is prohibited for use in any vehicle manufactured on or after January 1, 2028.

Section 619-D Enforcement

The New York Commissioner of Labor must enforce these laws. In addition, the New York State Attorney General shall have the power to enforce these laws.

New York Laws Vehicle and Traffic (VAT)¹⁵

Article 5 PERIODIC INSPECTION OF MOTOR VEHICLES¹⁶ [Existing]

301 Periodic inspection of all motor vehicles. [Existing]

301(g) The Commissioner must implement a program of motor vehicle lighting inspections which includes, but is not limited to, ensuring that vehicle headlamps, Daytime Running Lamps, backup lamps, tail lamps, and stop lamps do not exceed legal limits. [New]

¹⁵ <https://www.nysenate.gov/legislation/laws/VAT>

¹⁶ <https://www.nysenate.gov/legislation/laws/VAT/T3A5>

Article 9 EQUIPMENT OF MOTOR VEHICLES AND MOTORCYCLES¹⁷ [Existing]

376 Lamps, signaling devices, and reflectors on vehicles¹⁸ [Existing]

376.3 "No light having a candlepower rating in excess of thirty-two candle power shall be used on any vehicle, unless it is of a type approved by the commissioner." [Repeal]

376.3 "No vehicle headlamp having a luminous intensity exceeding 20,000 candelas for lower beams or 75,000 candelas for upper beams measured at any spatial location 30 meters from the source may be used in any vehicle manufactured on or after January 1, 2028. No headlamp, Daytime Running Lamp, backup lamp, tail lamp, or stop lamp having a Correlated Color Temperature exceeding 2900 Kelvin may be used in any vehicle manufactured on or after January 1, 2028." [New]

New York Codes, Rules and Regulations Title 15 Department of Motor Vehicles [Existing]

Chapter I – Regulations of the Commissioner¹⁹ [Existing]

Subchapter D – Equipment [Existing]

Part 43 – Motor Vehicle Lighting [Existing]

Section 43.8²⁰ [Repeal]

Subchapter F – Businesses Requiring Licenses [Existing]

Part 79 - Motor Vehicle Inspection²¹ [Existing]

Section 79.21 – Inspection of Motor Vehicles²² [Existing]

79.21(e) – Lighting and Reflectors [Existing]

79.21(e)(9) – Lighting Limits [New]

Reject if:

¹⁷ <https://www.nysenate.gov/legislation/laws/VAT/T3A9>

¹⁸ <https://law.justia.com/codes/new-york/vat/title-3/article-9/376/>

¹⁹ <https://regulations.justia.com/states/new-york/title-15/chapter-i/subchapter-d/part-43/>

²⁰ <https://regulations.justia.com/states/new-york/title-15/chapter-i/subchapter-d/part-43/section-43-8/>

²¹ <https://casetext.com/regulation/new-york-codes-rules-and-regulations/title-15-department-of-motor-vehicles/chapter-i-regulations-of-the-commissioner/subchapter-f-businesses-requiring-licenses/part-79-motor-vehicle-inspection>

²² <https://casetext.com/regulation/new-york-codes-rules-and-regulations/title-15-department-of-motor-vehicles/chapter-i-regulations-of-the-commissioner/subchapter-f-businesses-requiring-licenses/part-79-motor-vehicle-inspection/section-7921-inspection-of-motor-vehicles>

- Luminous Intensity for any headlamp used in any vehicle manufactured on or after January 1, 2028, exceeds 20,000 candelas for lower beams or 75,000 candelas for upper beams at any location when measured at all spatial locations 30 meters from the light source.
- Correlated Color Temperature for any headlamp, Daytime Running Lamp, backup lamp, tail lamp, or stop lamp used in any vehicle manufactured on or after January 1, 2028, exceeds 2900 Kelvin.

Questions and Concerns

1. Can New York State regulate the sale of OEM parts? Yes. For example, if New York decides that there is insufficient protection of public safety regarding OEM LED headlamps due to lack of regulation from NHTSA in FMVSS-108, then New York may establish its own safety requirements, such as limiting intensity to 20,000 candelas for lower beams and limiting CCT to 2900K.
2. Can the New York law for regulating LED headlamps be phased in? Yes. It would be wise to give the automakers the lead time to design and produce vehicles with safer headlamps. 3-5 years is the lead time required for the automakers. This is addressed in the Proposed Legislation below.
3. Trying to regulate OEM headlamps seems difficult. Can't New York just regulate aftermarket LED headlamps? The majority of the problem with LED headlamps are OEM headlamps. While aftermarket LED headlamps are definitely a problem, a new law targeting only aftermarket LED headlamps would only make a small dent in the entire problem. The Proposed Legislation below addresses this issue by requiring all headlamps to be 2900K or less on or after January 1, 2028. The Proposed Legislation also restricts the sale of aftermarket LED headlamps beginning January 1, 2026 to 20,000 candelas or less for lower beams and 75,000 candelas or less for upper beams for all points in space.
4. How will the inspectors at the inspection station know if a headlamp is OEM or aftermarket? There may not be a way for the inspector to know if an LED headlamp is OEM or aftermarket. This is a strong argument for why New York should not attempt to regulate only aftermarket headlamps and should instead regulate both OEM and aftermarket headlamps.

References

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2. 49 U.S.C. Chapter 301 Motor Vehicle Safety - <https://www.law.cornell.edu/uscode/text/49/subtitle-VI/part-A/chapter-301>
3. NHTSA FMVSS-108 2008 Update - Federal Motor Vehicle Safety Standards; Lamps, Reflective Devices, and Associated Equipment - <https://www.federalregister.gov/documents/2007/12/04/07-5644/federal-motor-vehicle-safety-standards-lamps-reflective-devices-and-associated-equipment>
4. California Vehicle Code Section 24409 – Low beams are considered non-glare by definition. <https://codes.findlaw.com/ca/vehicle-code/veh-sect-24409/>

5. 49 U.S.C. Chapter 301 Section 30103 – Relationship to Other Laws - <https://www.law.cornell.edu/uscode/text/49/30103>
6. California Passive Intelligent Speed Assistance Bill - <https://atrn.assembly.ca.gov/system/files/2024-06/sb-961-wiener.pdf>