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IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

MARK BAKER,

PLAINTIFF

V.

UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL.,

DEFENDANTS

Case No.: 2:24-cv-02558-DC-SCR

OBJECTIONS TO MAGISTRATE JUDGE'S FINDINGS AND RECOMMENDATIONS.

PLAINTIFF'S OBJECTION TO MAGISTRATE JUDGE SEAN RIORDAN'S FINDINGS AND RECOMMENDATIONS REGARDING THE DEFENDANT'S MOTION TO DISMISS

Background

Over the past 150 years, humans have invented an extraordinary number of products which emit electromagnetic radiation. In the first half of the 20th century, products such as televisions, x-ray machines, and lasers were created. As a result, millions of Americans were exposed to hazardous electromagnetic radiation, and thousands became ill, and many died.

Congress eventually recognized the need to protect the public from electromagnetic radiation and, in 1968, passed the Radiation Control for Health and Safety Act. Today, the U.S.

Food and Drug Administration ("FDA") is the agency with the responsibility and authority to protect the public from unnecessary electromagnetic radiation as per 21 U.S. Code Chapter 9 Subchapter V Part C - Electronic Product Radiation Control.

Similarly, in the first half of the 20th century, Americans began driving automobiles and, consequently, began dying in large numbers due to vehicle crashes. Congress passed the National Traffic and Motor Vehicle Safety Act in 1966 to protect the public from the dangers of automobile travel. Today, the National Highway Traffic Safety Administration ("NHTSA") is the federal agency mandated by Congress to publish performance standards for vehicle safety.

The invention of high-powered Light Emitting Diodes ("LEDs") has allowed automobile manufacturers to build and sell their vehicles using LED headlamps. LED headlamps emit a powerful, intense light, often with a large spike of hazardous blue-wavelength light that can cause permanent eye damage, and which can create debilitating glare. NHTSA and the FDA have received thousands of reports of harm from exposure to the light emitted by LED headlamps, and yet both agencies have failed to address the issues.

Congress has already established a legal structure to ensure that public health and safety are protected in such situations. 21 U.S.C. § 360ii directs the FDA to establish and carry out an electronic product radiation control program to protect public health and safety and Congress has explicitly directed the FDA to establish and maintain a liaison with federal agencies such as NHTSA on techniques, equipment, and programs for testing and evaluating electronic product radiation. However, the FDA has failed to comply 21 U.S.C. § 360ii and has declined to collaborate with NHTSA on testing and evaluating LED headlamps.

NHTSA publishes vehicle headlamp standards in 49 C.F.R. § 571.108 but has failed to update 49 C.F.R. § 571.108 to address eye safety and glare issues from LED headlamps.

Congress has directed the FDA and NHTSA to collaborate on such issues, but rather than collaborating and addressing the health and safety impacts of LED headlamps, NHTSA and the FDA have chosen to ignore the issues. There is currently a regulatory vacuum for LED headlamps which needs to be solved.

Mark Baker, President of the Soft Lights Foundation, as a Pro Se litigant, petitioned the Court to compel the FDA to establish and maintain a liaison with NHTSA to test and evaluate LED vehicle headlamps as required by 21 U.S.C. § 360ii(a)(6)(A) to fill the regulatory void. On September 16, 2025, Magistrate Judge Sean Riordan issued Findings and Recommendations that the Defendant's Motion to Dismiss be granted and that Mr. Baker's petition be dismissed without leave to amend.

However, as set forth below, the magistrate judge made multiple errors. The magistrate judge incorrectly concluded that the FDA has unlimited discretion in deciding how to establish and carry out an electronic radiation control program to protect the health and safety of the public. The magistrate judge also misunderstood the Petitioner's request and wrongly asserted that the Petitioner is requesting that the Court compel the FDA to publish performance standards for LED headlamps.

Procedural History

FDA Petitions

On June 13, 2022, the Soft Lights Foundation petitioned the FDA to regulate LED products. On January 22, 2023, the Soft Lights Foundation petitioned the FDA to regulate LED flashing lights. On September 7, 2023, the Soft Lights Foundation petitioned the FDA to

regulate LED vehicle headlamps. On September 11, 2023, the Soft Lights Foundation petitioned the FDA to regulate LED streetlights.

On May 28, 2024, the FDA denied all four Soft Lights Foundation petitions with a single 19-page letter which relied exclusively on information from an unknown company with unknown qualifications. The denial letter did not address the adverse impacts of LED vehicle headlamps, nor did the letter provide any of the evidence that the FDA relied on while making its determination to deny the petition to regulate LED vehicle headlamps.

NHTSA Petitions

On August 5, 2022, the Soft Lights Foundation petitioned NHTSA to issue an order of non-compliance to Ford for non-compliant LED headlamps. On December 2, 2022, NHTSA denied the petition, stating "NHTSA, as an agency focused on automotive safety, also recognizes the expertise of its sister agencies that are health-focused, such as the FDA."

On March 1, 2024, the Soft Lights Foundation petitioned NHTSA to set an overall limit on headlamp intensity. On May 15, 2024, the Soft Lights Foundation petitioned NHTSA to set a limit on Correlated Color Temperature. NHTSA has not made a determination on either petition.

First Lawsuit

On January 22, 2024, Mark Baker, President of the Soft Lights Foundation, filed a Pro Se lawsuit against the FDA to compel compliance with 21 U.S.C 360ii(a) and publish performance standards for LED products. The FDA filed a Motion to Dismiss. After an initial hearing with the magistrate judge, Mr. Baker voluntarily dismissed the lawsuit on September 26, 2024, after deciding that the lawsuit was overbroad.

Second Lawsuit

On September 23, 2024, Mark Baker filed a lawsuit against the FDA and NHTSA for failing to comply with 21 U.S.C 360ii(a)(6)(A) and establish and maintain a liaison to test and evaluate LED headlamps. The FDA and NHTSA filed a Motion to Dismiss.

On September 16, 2025, Magistrate Judge Sean Riordan issued Findings and Recommendations that the Defendant's Motion to Dismiss should be granted.

The Plaintiff now submits these Objections to the magistrate judge's findings and recommendations.

Standard of Review

The district judge reviews a magistrate judge's report and recommendation de novo. Fed. R. Civ. P. 72(b)(3). "The district judge may accept, reject, or modify the recommended disposition; receive further evidence; or return the matter to the magistrate judge with instructions." *Id*.

An agency's actions or inactions are subject to judicial review if an agency's decisions are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29 (1983). Here, the FDA has acted arbitrarily and capriciously by choosing to ignore the adverse health and safety impacts of the visible light radiation emitted by LED headlamps, and the FDA has abused its discretion by failing to adequately establish and maintain a liaison with NHTSA to address the issue.

Objections

Plaintiff objects to the magistrate judge's Findings and Recommendations on five grounds: First, the magistrate judge wrongly ignored 21 U.S.C. § 360ii(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." The FDA's current electronic product radiation control program is defective and inadequate because it is not protecting the public health and safety from electronic product radiation, including LED headlamps.

Second, the magistrate judge misinterprets the Plaintiff's request as being a request to have the Court compel the FDA to publish regulations for LED headlamps. The Plaintiff's request is to have the Court compel the FDA and NHTSA to establish and maintain a liaison to test and evaluate LED headlamps, as required by 21 U.S.C. § 360ii(a)(6)(A).

Third, the magistrate judge incorrectly concluded that, "Plaintiff's reading would arguably require the FDA to engage in inter-agency consultations for each of the innumerable everyday electronic products that emit radiation." The plaintiff is not requesting the FDA to engage in inter-agency consultations for all electronic products. The Plaintiff is requesting only a liaison between the FDA and NHTSA for one product: LED headlamps.

Fourth, the magistrate judge incorrectly combines the Plaintiff's first lawsuit with the second lawsuit, when the first lawsuit was primarily about discretionary FDA actions, and the second lawsuit is solely about non-discretionary actions.

Fifth, the magistrate judge has wrongly concluded that the FDA has acted in compliance with the Administrative Procedure Act ("APA") and has made its decision to not collaborate with NHTSA on LED headlamps based on all available evidence and reasoned decision making.

In fact, the FDA has acted arbitrarily and capriciously and has abused its discretion. Under 5 U.S. Code § 706, the Court shall hold unlawful the FDA's decisions.

I. The Court Wrongly Ignores 21 U.S.C. § 360ii(a) Which Mandates that the FDA Protect the Public Health and Safety from Electronic Product Radiation.

21 U.S.C. § 360ii(a) states, "The Secretary shall establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation." The term "shall" means an imperative, non-discretionary, and mandatory action.

Thus, Congress has recognized that electromagnetic radiation, while useful for accomplishing certain tasks, is also hazardous and must be appropriately regulated. Congress granted the authority to protect the public health and safety from electromagnetic radiation from electronic products to the FDA. Congress additionally directed the FDA to collaborate with other federal agencies to ensure that the electronic radiation control program is effective.

Congress made it mandatory that the FDA "establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation." A radiation control program that is not properly designed to protect the public health and safety from electronic product radiation does not meet the requirements of 21 U.S.C. § 360ii(a). If the radiation control program is defective and is not functioning to adequately protect public health and safety, then the program is in violation of 21 U.S.C. § 360ii(a).

The FDA's electronic product radiation control program is improperly designed and not adequately operating because the program has failed to protect the public from the hazardous

blue-wavelength light emitted by LED headlamps which are causing eye injuries, impairing vision, and putting public health and safety at risk. Blue-rich LED headlamps are likely to cause long-term cumulative eye damage, and yet the FDA's defective electronic product radiation control program is not addressing the problem. As part of a properly functioning electronic product radiation control program, the FDA must establish and maintain a liaison with NHTSA to test and evaluate LED headlamps to ensure that long term eye damage does not occur.

There is clear and convincing evidence that LED headlamps have caused, and are causing, harm to the public, and that LED headlamps present a safety hazard due to their extreme intensity and extreme glare. NHTSA has received signatures from nearly 75,000 individuals requesting that NHTSA take action to address blinding LED headlights, and over 3,000 written reports of harm. The FDA has received approximately 350 reports of harm from exposure to LED products, many of which relate to LED vehicle headlamps.

Numerous research studies have shown that blue wavelength light and LED light is a photobiological hazard. For example below are the titles of a few research articles.

- Accidental macular injury from short-term exposure to a handheld high-intensity LED light[1]
- The blue light hazard and its use on the evaluation of photochemical risk for domestic lighting. An *in vivo* study[2]

[1] https://pmc.ncbi.nlm.nih.gov/articles/PMC10404656/
[2] https://www.sciencedirect.com/science/article/pii/S0160412024000576

- Blue light exposure collapses the inner blood-retinal barrier by accelerating endothelial CLDN5 degradation through the disturbance of GNAZ and the activation of ADAM17[3]
- Mitochondria as Potential Targets and Initiators of the Blue Light Hazard to the Retina[4]

Because there have been so many reports of harm from exposure to LED headlamps, the Congressional House Committee on Appropriations unanimously approved an amendment to the Fiscal Year 2026 Appropriations Bill, requesting that NHTSA report to Congress on the impacts of low beam headlamps on vision and safety.[5]

If there was every indication that the visible light radiation emitted by LED headlamps was benign, then the magistrate judge may have rightly decided that the Court did not have the authority to compel the FDA to take action on LED headlamps. But since there is overwhelming evidence that LED headlamps emit hazardous visible light radiation, the magistrate judge has wrongly determined that the FDA has no requirement to establish and maintain a liaison with NHTSA to test and evaluate LED headlamps.

The FDA has provided no evidence that the FDA should not collaborate with NHTSA. The Administrative Procedure Act requires the FDA to engage in reasoned decision making. This means that, if the FDA has decided not to collaborate with NHTSA on LED headlamps, the FDA must document its findings. The FDA has failed to do so, and has instead acted arbitrarily and capriciously.

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[3] https://www.researchgate.net/publication/370226596_Blue_light_exposure_collapses_the_inner_blood-retinal_barrier_by_accelerating_endothelial_CLDN5_degradation_through_the_disturbance_of_GNAZ_and_the_activation_of_ADAM17

[4] https://pmc.ncbi.nlm.nih.gov/articles/PMC6721470/

[5] https://www.congress.gov/committee-report/119th-congress/house-report/212/1

While the FDA could develop performance standards for LED headlamps on its own, Congress has already established that the FDA should instead collaborate with NHTSA and then let NHTSA publish the proper performance standards in 49 C.F.R. § 571.108 to ensure that LED headlamps do not cause eye injuries.

Hundreds or thousands of research studies have proven that blue wavelength light is a photobiological hazard. Nearly 75,000 individuals have petitioned NHTSA to take action on LED vehicle headlamps because they impair vision and make driving dangerous. NHTSA and the FDA have received thousands of reports of harm from exposure to LED vehicle headlamps. Congress has asked NHTSA to do something about LED vehicle headlamps. A social media site now contains hundreds or thousands of photographs and descriptions of hazardous LED vehicle headlamps. There is no doubt that LED headlamps are hazardous and dangerous, and yet the FDA unjustifiably claims that the FDA need not include LED headlamps as part of its electronic product radiation control program, and that the FDA need not liaise with NHTSA on the issue of LED headlamps.

The magistrate judge's Findings and Recommendations wrongly ignore the FDA's mandatory, non-discretionary duty to establish and carry out a properly designed and adequately functioning electronic product radiation control program that includes LED headlamps. The FDA's decision to ignore the health and safety impacts of LED vehicle headlamps was decided arbitrarily and capriciously and is an abuse of discretion, and this Court should reject the magistrate judge's recommended disposition of this case.

II. The Court Wrongly Interprets that the Petitioner is Requesting that the Court Compel the FDA to Regulate LED Vehicle Headlamps.

The magistrate judge wrote, "As Defendants reason, neither the required liaison nor the constitution of the Safety Committee would be likely to change their decision not to regulate LEDs in the manner Plaintiff requests, further showing that redressability is lacking." (F&R p.8, line 1). The magistrate judge also wrote, "Other statutory provisions demonstrates that Congress did not require the FDA to engage in the regulation of LED lights specifically." (F&R p.14 line 10).

But the Petitioner did not request that the Court compel the FDA to regulate LED vehicle headlamps.

The relief requested in the petition is, "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."

The magistrate judge has misunderstood the Petitioner's request. NHTSA regulates vehicle headlamps in the Federal Motor Vehicle Safety Standard, 49 C.F.R. § 571.108, not the FDA. But NHTSA has not regulated the special characteristics of LED vehicle headlamps to protect public health and safety because NHTSA defers to the FDA for protecting public health and safety from electromagnetic radiation. This means that NHTSA relies on the FDA to determine what intensity levels and what levels of blue-wavelength light are safe for the eyes.

In the December 2, 2022, petition denial letter, NHTSA wrote, "NHTSA also wants to express appreciation to the Petitioner for bringing to its attention health concerns that the Petitioner associates with LED headlamps. NHTSA takes these concerns seriously. NHTSA, as

an agency focused on automotive safety, also recognizes the expertise of its sister agencies that are health-focused, such as the FDA."

There is a regulatory void where neither NHTSA nor the FDA have acted to address the eye safety issues of LED vehicle headlamps. This regulatory void should not exist because Congress already laid out perfectly how the federal agencies should work together to protect public health and safety.

Congress placed the FDA in charge of electromagnetic radiation and directed the FDA to "establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation." Congress instructed the FDA to "consult and maintain liaison with…other appropriate Federal departments and agencies on techniques, equipment, and programs for testing and evaluating electronic product radiation." (21 U.S.C. § 360ii(a)).

If the FDA had adequately established and carried out a a properly functioning electronic radiation control program, the FDA would have established and maintained a liaison with NHTSA for LED headlamps. If the FDA had properly established and maintained a liaison with NHTSA, then the two agencies would have tested and evaluated electronic product radiation from products such as LED vehicle headlamps. If the FDA and NHTSA had properly tested and evaluated LED headlamps, certainly NHTSA would have updated 49 C.F.R. § 571.108 to set limits on intensity and blue-wavelength light for LED headlamps to limit glare and protect the eyes.

But the FDA failed the first step of establishing and carrying out a properly functioning electronic product radiation control program. The Petitioner is requesting that the Court compel the FDA and NHTSA to comply with 21 U.S.C. § 360ii(a)(6)(A) and establish and maintain a

liaison as part of a properly functioning electronic product radiation control program designed to protect public health and safety.

The Petitioner is not requesting that the Court compel the FDA to publish performance standards for LED headlamps. While the FDA certainly has been given the authority to regulate LED headlamps, the FDA has discretionary authority as to whether LED headlamps should be regulated by the FDA. In this situation, the most logical agency for publishing performance standards for LED headlamps is NHTSA. The magistrate judge's mistaken belief that the Petitioner is requesting that the Court compel the FDA to regulate LED headlamps should be rejected by this Court.

III. The Court Wrongly Asserts that the Petitioner's Request Requires Inter-Agency Consultations for Every Electronic Product.

The magistrate judge wrote, "Plaintiff's reading would arguably require the FDA to engage in inter-agency consultations for each of the innumerable everyday electronic products that emit radiation." But the Plaintiff did not request that the FDA engage in inter-agency consultations for all electronic products. The Petition is narrowly focused on the FDA's liaison with a single federal agency: NHTSA. The Petition is narrowly focused on a single electronic product: LED vehicle headlamps. The magistrate judge has taken this very narrow request and expanded it to include all electronic products and all federal agencies. This is not the Plaintiff's request.

The Petitioner is requesting that the Court compel the FDA to establish and maintain a liaison with NHTSA to test and evaluate LED headlamps which are featured in the news frequently due to the serious adverse impacts caused by the visible light radiation emitted by

LED headlamps. Below are some of the news stories on the adverse impacts of LED vehicle headlamps for 2024 and 2025.

August 4, 2025 – Lights Are Brighter Than Ever. Is That Bad for Your Eyes?

April 5, 2025 – Why are car headlights so blindingly bright now?

February 5, 2025 – Headlights really are brighter these days. How to deal with LED glare

December 4, 2024 – Report: How Headlight Glare Became Such a Big Problem

December 3, 2024 – Asleep at the Wheel in the Headlight Brightness Wars

October 31, 2024 – Headlights Are too Bright! But US Experts Say Their Not Bright Enough.

September 25, 2024 – Garbage Truck Overturns

September 15, 2024 – These LED headlights are causing problems in the US – American drivers have decided

July 20, 2024 – Annoyed by headlight glare at night? You're not alone. Here's why it's become a problem.

May 12, 2024 – Elana Scherr: Are Modern Headlights Too Bright?

April 24, 2024 – Vehicles with White LED Headlights to Face Legal Action in this Indian State

April 4, 2024 – 5 On Your Side: New headlights could end nighttime blinding, but haven't hit US roads yet

April 2, 2024 – The Problem with LED Headlights

April 2, 2024 – Ministers to launch review into headlight glare as drivers report being dazzled

March 29, 2024 – America's Drivers Agree: LED Headlights Are Just too Bright

March 19, 2024 – Why Are Headlights So Bright? There May Be a Fix, But It's Complicated

January 17, 2024 – The Maine Millennial: Car Headlights Are Out of Control

January 6, 2024 – Urgent Warning Over 'Blinding' New-style Headlights Experts Label as "Potential Killers" – Is Your Car Affected?

The FDA has not differentiated between electronic products that are clearly causing harm, such as LED headlamps, and electronic products that show little indication of harm. The FDA may in fact need to test and evaluate other electronic products such as LED flashing lights, but this petition does not address any product other than LED headlamps, and the Plaintiff is not asking the Court to compel the FDA to address the health and safety issues of any product other than LED headlamps.

The magistrate judge has wrongly expanded the scope of the Plaintiff's request and then wrongly concluded that the Defendant's Motion to Dismiss should be granted. This Court should reject the magistrate judge's unjustified expansion in scope and should reject the magistrate judge's recommended disposition of this case

IV. The Court Wrongly Combines Two Lawsuits into One.

The magistrate judge wrote, "Plaintiff filed the complaint in this case shortly after moving to voluntarily dismiss a related case in the wake of a hearing on the defendants' motion to dismiss in that case. See supra n.3. That case also concerned the FDA's failure to regulate LED lights, included similar causes of action as set out in this case, and included several of the

same defendants. The complaint in the instant case is in substance an amendment of the complaint in that earlier case, which narrowed the scope of Plaintiff's causes of action while adding the NHTSA defendants. The fact that Plaintiff has now filed two similar actions counsels against further amendment." (F&R, p. 15, line 4).

The magistrate judge wrongly claims that the first lawsuit, which was voluntarily dismissed by the Plaintiff due to Plaintiff's belief that the first lawsuit was overly broad, "included similar causes of action as set out in this case." The first lawsuit requested several discretionary actions, with most of those requests asking the court to compel the FDA to publish performance standards for electronic products.

This lawsuit requests only that the Court compel the FDA to comply with the non-discretionary requirement of 21 U.S.C. § 360ii(a)(6)(A). This case is not an amendment of the first case, but an entirely different case. This case is not about the FDA's failure to regulate LED products, but about the FDA's failure to establish and maintain a liaison with NHTSA to test and evaluate a single harmful product: LED headlamps.

The magistrate judge has overstepped his authority in claiming that "The complaint in the instant case is in substance an amendment of the complaint in that earlier case." The first case was primarily based on discretionary FDA actions, while the second case is based solely on a non-discretionary action. The first case was not adjudicated on the merits, and thus nothing was established in the first case. "[T]here must be at least one decision on a right between the parties before there can be said to be a termination of the controversy, and before a judgment can avail as a bar to a subsequent suit. . . . There must have been a right adjudicated or released in the first suit to make it a bar, and this fact must appear affirmatively." (*Costello v. United States* (1961)).

This Court should reject the magistrate judge's decision to merge the voluntarily dismissed lawsuit with this lawsuit to ensure a fair hearing on the merits of this case. Permitting the unadjudicated issues of the first case to taint the second case would cause a grave injustice.

V. The Court Incorrectly Concludes that the FDA has Complied with the Administrative Procedure Act.

The magistrate judge wrote, "Contrary to Plaintiff's reading, 21 U.S.C. § 360ii(a)(6)(A) does not contain a discrete, mandatory directive for FDA to act with respect to any specific type of radiation-emitting product, such as LED lights generally or LED headlamps specifically."

The magistrate judge concludes that, because there is no mandatory requirement for the FDA to act with respect to LED headlamps in particular, that the FDA thus has the discretion to take no action on LED headlamps. The magistrate judge's conclusion is incorrect because the Administrative Procedure Act requires the FDA to use reasoned decision making and to consider all available evidence. In the case of LED headlamps, the FDA has abused its discretion by failing to adequately consider the thousands of reports of harm and adverse impacts of LED headlamps and blue-rich light on public health and safety.

The Court refers to a 19-page Final Response Letter from the FDA and stated, "The FDA provided several reasons for denying the requests, including that (1) "regulations for specific performance standards for every type of electronic product" are not "necessary given the effectiveness of existing mitigations in addressing unnecessary radiation and alternative approaches to protect public health" and "the fact that most products do not produce types of levels of unnecessary radiation that pose a risk to public health"; (2) specific standards for LEDs are not necessary "due to their long history of safety with respect to the visible wavelengths

being emitted," and (3) the Soft Lights Foundation had provided insufficient evidence that the requested standards are necessary. Id. at 6-7."

It is critical for this Court to understand that the FDA's May 28, 2024, 19-page Final Response Letter is based solely on recommendations from an unknown outside company with unknown qualifications. The FDA wrote, "FDA engaged an independent, third-party organization to conduct a comprehensive literature search and systematic review to identify the current state of knowledge with regard to adverse health effects of LED light on humans." The supposed analysis of LED light on human health by the unknown company has not been made public and was withheld from a Freedom of Information Act ("FOIA") request by the Soft Lights Foundation. The only document that the FDA released in response to the FOIA was the 19-page Final Response Letter. None of the underlying analysis was provided by the FDA. By withholding the name and credentials of the third-party company and by not making public the analysis used in its decision-making process, the FDA is acting in bad faith.

Nothing is known about this "independent, third-party organization." Why would the FDA choose to outsource the research on the impacts of LED light to an unknown third party, when Congress has already mandated that the FDA consult with the Technical Electronic Product Safety Standards Committee ("TEPRSSC")? TEPRSSC is required to consist of members of the public, government officials, and industry officials and to meet and discuss electronic product safety in public. The most logical conclusion is that the FDA acted in bad faith and contracted with the unknown third-party to avoid public scrutiny.

In the 19-page Final Response Letter, the FDA wrote, "FDA has determined that the information provided in support of CP3 is insufficient to demonstrate a performance standard to control the emission of electronic product radiation by LED products that use LEDs that are used

on vehicles…is necessary at this time for the protection of the public health and safety." (FRL p. 17). But in reaching this conclusion, the FDA relied solely on the recommendations provided by the third-party company and ignored the nearly 75,000 individuals who have reported to NHTSA and the FDA that LED headlamps are a health and safety hazard.

Regardless, in this situation the Petitioner is not asking the FDA to establish performance standards for LED headlamps. The Petitioner is asking the Court to compel the FDA and NHTSA to comply with 21 U.S.C. § 360ii(a)(6)(A) and establish and maintain a liaison as part of a properly functioning radiation control program designed to protect public health and safety.

5 U.S.C. § 706 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, (1) the reviewing court shall compel agency action unlawfully withheld or unreasonably delayed; and (2) hold unlawful and set aside agency action, findings, and conclusions found to be (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;."

The FDA has abused its discretion in deciding not to establish and maintain a liaison with NHTSA to test and evaluate LED headlamps. The FDA has provided no evidence to justify its conclusions. **If the FDA truly believes that the FDA is not required to establish and maintain a liaison with NHTSA to test and evaluate LED headlamps, the FDA must provide an affirmative, written report which addresses the reported complaints of harm from exposure to LED headlamps, analyzes the hundreds of research papers on blue-light toxicity, and details why LED headlamps do not need testing and evaluation**. Without such a report, the FDA's decision to not collaborate with NHTSA to test and evaluate LED headlamps is arbitrary and capricious and an abuse of discretion.

This Court may not simply defer to the FDA's decision to not comply with 21 U.S.C. § 360ii(a)(6)(A) for LED headlamps. This Court must exercise its independent judgment in deciding whether the FDA has acted within its statutory authority, and this Court may not defer to the FDA's interpretation of the law. (*Loper Bright Enterprises et al. v. Raimondo, Secretary of Commerce, et al.* (2024)). This Court should acknowledge the magistrate judge's failure to properly apply 5 U.S.C. § 706 and should reject the magistrate judge's recommended disposition.

Conclusion

For the reasons stated above, this Court should reject the magistrate judge's recommended disposition of granting the Defendant's Motion to Dismiss. Instead, this Court should issue an order directing 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 headlamps to ensure the photobiological, neurological, psychological, and hormonal health and safety of all individuals.

Dated: September 23, 2025

Respectfully Submitted,

By: /s/ Mark Baker
In Pro Per