October 23, 2026

Mark Baker
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Sent via email to: mbaker@softlights.org

Re: Citizen Petition – Docket Number FDA-2026-P-0028

Dear Petitioner:

This letter responds to your citizen petition dated December 30, 2025, requesting that the Food and Drug Administration (FDA or Agency) "comply with 21 U.S.C. 360jj(a)(2) [section 533(a)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)], which directs...[FDA] to conduct '[a] study to determine the necessity for the development of standards for the use of nonmedical electronic products for commercial and industrial purposes' and provide a report to Congress."[1] The petition specifically requests that FDA initiate a study and submit a report related to light emitting diode (LED) products.

We have carefully reviewed information provided in the citizen petition and petition attachments, as well as public comments submitted to the public docket established for the petition, and, for the reasons described below, in accordance with 21 CFR 10.30(e), the petition is denied.

I. Action Requested

In your petition, you request that FDA "comply with [section 533(a)(2) of the FD&C Act]" with a focus on LED products. Specifically, the petition requests that FDA "initiate a study and submit a report to Congress on the photobiological, neurological, psychological, hormonal, and other health hazards of LED products, the measures necessary to assure the comfort, health, safety, and civil rights of the public from the hazards of LED Visible Light radiation, and the cooperation needed between the FDA and other federal agencies to implement a properly functioning radiation control program for LED products."[2]

II. Legal Background

FDA is responsible for regulating radiation-emitting electronic products through the Radiation Control provisions of the FD&C Act (originally enacted as the Radiation Control for Health and

[1] Petition at 2.
[2] *Id*.

Safety Act of 1968), which are in sections 531 through 542 of the FD&C Act ("Radiation Control" or "EPRC" provisions). The Radiation Control provisions apply to any "electronic product," which is defined as: "(A) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or (B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation" (section 531(2) of the FD&C Act; see also 21 CFR 1000.3(j)). Electronic products include products that emit visible light such as LED products.

Section 533(a)(2) of the FD&C Act provides: "(a) The Secretary shall conduct the following studies, and shall make a report or reports of the results of such studies to the Congress on or before January 1, 1970, and from time to time thereafter as he may find necessary, together with such recommendations for legislation as he may deem appropriate...(2) A study to determine the necessity for the development of standards for the use of nonmedical electronic products for commercial and industrial purposes...."

III. Discussion

Your petition asks FDA to carry out actions that you contend are required by section 533(a)(2) of the FD&C Act. For instance, the petition requests that FDA "comply with [section 533(a)(2)] and submit reports to Congress on the impacts of LED products on human health and safety,"[3] and states that "[a]ny decision by the FDA to not submit a report to Congress on the hazards of LED products would require a detailed justification as to why such as [sic] report is not beneficial for members of Congress."[4]

Initially, FDA disagrees with several aspects of your interpretation of the statute. To the extent the petition requests that FDA "comply with"[5] section 533(a)(2) of the FD&C Act and asserts that "FDA is required by [section 533(a)(2) of the FD&C Act] to study the impacts of LED products and submit a report to Congress,"[6, 7], we disagree with your interpretation, including that section 533(a)—which requires FDA to initiate a study relating to *nonmedical electronic products*— requires FDA to initiate a study for any particular nonmedical electronic product or

[3] Petition at 4.
[4] Petition at 9.
[5] Petition at 2.
[6] Petition at 10.
[7] This response assumes, for the sake of argument—and without deciding—that this request is appropriate for a citizen petition under 21 CFR 10.30. However, we note that, in accordance with 21 CFR 10.30, a petition must request the Commissioner of Food and Drugs to "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action" (21 CFR 10.30(b)(3)), and must specify "the specific action or relief requested." See 21 CFR 10.30(b)(3). Assertions that section 533(a)(2) imposes certain legal requirements on FDA are not requests to "take or refrain from taking" an administrative action and so are not the appropriate subjects of a citizen petition under 21 CFR 10.30.

for LEDs specifically. To the extent the petition asserts that it would be an "abuse of discretion" by FDA to decline to study the impacts of LED products and submit a report to Congress,[8] we disagree with your assertion; we believe FDA has appropriately examined the scientific and technical issues and determined that such a study and report are not warranted at this time for the reasons discussed below. Your petition also requests that FDA comply with section 533(a)(2) by "initiat[ing] a study...on...the cooperation needed between the FDA and other federal agencies to implement a properly functioning radiation control program for LED products."[9] This request is outside the scope of section 533(a)(2), which describes a study to "determine the necessity for the development of standards for the use of nonmedical electronic products for commercial and industrial purposes." You also request that FDA "initiate a study and submit a report to Congress on...the measures necessary to assure...the civil rights of the public from the hazards of LED Visible Light radiation..." [10] We note that FDA is not directly responsible for enforcing civil rights laws.

To the extent your requests that FDA initiate a study and submit a report to Congress are within the scope of section 533(a)(2), FDA has not found that a study to determine the necessity for the development of standards for the use of LED products (and a report to Congress about the results of such study) are necessary at this time. Your petition acknowledges that section 533(a)(2) of the FD&C Act gives FDA discretion to determine whether conducting the described study and submitting a report or reports to Congress after January 1, 1970, are necessary.[11]

First, FDA already monitors, studies, and evaluates impacts to public health and safety from radiation-emitting products, including non-ionizing and non-medical radiation emitting products such as LED products, to identify new risks and potential safety concerns consistent with our jurisdiction. For instance, FDA continues monitoring accidental radiation occurrence (ARO) reports for electronic products and reviewing other information submitted to the Agency, including information submitted specifically about individual experiences with LED products.[12] FDA engages with experts and undertakes research, including research on non-coherent light sources,[13] to identify the types of products where there is sufficiently clear and strong evidence

[8] Petition at 10. *See also* petition at 4.
[9] Petition at 2.
[10] *Id*.
[11] *See* petition at 4.
[12] This information includes information such as the "incident reports" submitted in Appendix F to your petition and the "reports of harm" and "incident reports" referenced in your petition, both of which you indicate have already been submitted to FDA. *See* Appendix F and petition at 3-4. FDA previously reviewed individual "incident"-type reports in connection with prior citizen petitions filed by Soft Lights Foundation (*See* FDA's May 24, 2024 response to citizen petitions filed by Soft Lights Foundation, Docket Numbers FDA-2022-P-1151, FDA-2023-P-0233, FDA-2023-P-3828, and FDA-2023-P-3879 ("2024 response"), available at https://www.regulations.gov/ using the petition docket number). The AROs and other information about individual experiences with LED products received to date, including the "incident reports" attached at Appendix F, do not appear to contain any substantially new information that would change our finding that a study to determine the necessity for the development of standards for the use of nonmedical electronic products for commercial and industrial purposes is not necessary at this time.
[13] See, e.g., James RH, Landry RJ, Walker BN, Ilev IK. "Evaluation of the Potential Optical Radiation Hazards with

of a risk to human health. FDA participates in certain standards organization meetings, such as meetings of the International Electrotechnical Commission (IEC), the internationally recognized standards committee overseeing the safety of lamp and lamp systems (among other products). FDA also monitors and reviews relevant information from other standards organizations, for example the American National Standard Institute/Illuminating Engineering Society (ANSI/IES) TM-39-25 "Technical Memorandum: Quantification and Specification of Visual Responses to Temporal Light Modulation (a.k.a. Flicker)" (2025)[14] and scientific bodies, for example the International Commission on Non-Ionizing Radiation Protection (ICNIRP)[15] "ICNIRP Statement on Short Wavelength Light Exposure from Indoor Artificial Sources and Human Health" (2024), which concluded that the data are insufficient to draw conclusions about certain physiological effects of short wavelength light exposure.[16] FDA attends and participates in international conferences[17] in the field of optics, lasers, and biophotonics where recent developments and applications in the area of LED technologies, among other topics, are presented and discussed. Experts within FDA also generally monitor and review relevant data, including the latest available scientific, medical, and technical data in the field of electronic product radiation, to evaluate the conditions of exposure to electronic product radiation and intense magnetic fields that may present a risk to human health. These activities assist the Agency in monitoring for new risks and changes in technology related to non-coherent light sources, including LED products, that may impact human health.

Moreover, in 2023, FDA engaged an independent third-party organization to conduct a comprehensive literature search and systematic review to identify the then-current state of knowledge with regard to adverse health effects of LED light on humans in peer-reviewed clinical and engineering literature (2023 literature search). This literature search considered various potential health effects of interest, including but not limited to behavioral, neurologic, physiological (including skin and eye), and psychological effects. Based on the results of the review, FDA determined that insufficient evidence existed in the literature at that time to demonstrate that a performance standard to control the emission of electronic product radiation

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Led Lamps Intended for Home Use," *Health Physics* 112(1):p 11-17, January 2017. | DOI: 10.1097/HP.0000000000000580; Landry RJ, James RH, Miller SA, Ilev IK. "Evaluation of Potential Optical Radiation Hazards from LED Flashlights," *Health Physics*. 2021 Jan;120(1):56-61. doi: 10.1097/HP.0000000000001283. PMID: 33264236.

[14] Available at https://store.ies.org/product/technical-memorandum-quantification-and-specification-of-visual-responses-to-temporal-light-modulation-a-k-a-flicker/?v=0b3b97fa6688.

[15] ICNIRP is an internationally recognized independent scientific body that prepares guidance and recommendations for protection from non-ionizing radiation based on established scientific principles. See https://www.icnirp.org/en/home/home-read-more.html?utm_source=chatgpt.com.

[16] Available at https://journals.lww.com/health-physics/fulltext/2024/04000/icnirp_statement_on_short_wavelength_light.7.aspx. The article discusses both primary effects (i.e., sleep-awake/circadian rhythms) and long-term secondary effects (e.g., cancer, etc.) of blue light and concludes that due to limited data available (e.g., insufficient number of well-conducted epidemiological studies with regards to potential long-term adverse effects) and conflicting results, there is insufficient evidence to draw any conclusions.

[17] For example, FDA has been involved as chairs and presenters at conferences sponsored by the Society of Photo-Optical Instrumentation Engineers (SPIE) and the Conference on Lasers and Electro-Optics (CLEO).

by products that use LEDs was necessary for the protection of public health and safety.[18]

Next, the petition contains several assertions about the impacts to health from LED products, but only loosely associates assertions regarding blue wavelength light emitted from LEDs (hereinafter referred to as "blue wavelength LED light") and pulsed LED lights with scientific evidence. Specifically, you assert that "[t]housands of peer-reviewed studies have shown blue wavelength light is emitted by many LED products, [and] is toxic and interferes with hormonal processes [and p]ulsed LED lights interfere with vision and cognitive functioning."[19] Accordingly, this response focuses on the peer-reviewed scientific, medical, and technical literature referenced in the petition attachments on the effects of blue wavelength LED light and pulsed LED light on human health.[20] We note that the petition attachments also include references to peer-reviewed studies about retinal hazards from white LED light and studies about glare. Although these references were not associated with assertions made in the petition, FDA nevertheless reviewed the studies and addresses them in this response. As discussed below, FDA did not find the information in the peer-reviewed literature sufficient to necessitate a study and report to Congress as requested in the petition.

For blue wavelength LED light, the majority of studies you referenced examining associations between artificial light at night (i.e., blue wavelength LED light) and secondary health outcomes – including cancer,[21] cardiovascular disease,[22] psychiatric disorders,[23] and metabolic effects[24] – rely on satellite-derived exposure estimates that do not characterize individual ocular exposure to

[18] Additional details about the literature search and results may be found in FDA's response to Soft Lights Foundation's citizen petitions filed under docket numbers FDA-2022-P-1151, FDA-2023-P-0233, FDA-2023-P-3828, and FDA-2023-P-3879 available at https://www.regulations.gov/ using the petition docket numbers.

[19] Your petition includes several attachments that provide lists of references on different topics related to LED light. However, other than blue wavelength and pulsed LED lights, the petition does not identify how the references support any specific action requested. As a result, while FDA reviewed the information in the attachments, the discussion in this response primarily focuses on those peer-reviewed articles referenced in the relevant attachments about blue wavelength and pulsed LED lights not previously reviewed by FDA. You also provided an attachment consisting of personal stories or experiences with LED lights, which the attachment indicated were already submitted to FDA (*see* Attachment F). As noted in our 2024 response, when making regulatory decisions, FDA generally gives scientific data and expert opinions much greater weight than personal stories or experiences because the latter report on the experience of a single individual, are difficult to generalize, and generally do not provide all factors that may be contributing to any adverse health effects, the extent of the population that may be impacted, under what conditions, and the characteristics of products, if any, that pose a risk

[20] We note that the 2023 literature search specifically included clinical and engineering literature on the effects of blue wavelength and pulsed LED light on human health, and effects on the retina from LED light, among other topics, within its scope.

[21] *See* Palomar-Cros, Anna, et al. "Indoor and outdoor artificial light-at-night (ALAN) and cancer risk: a systematic review and meta-analysis of multiple cancer sites and with a critical appraisal of exposure assessment." *Science of The Total Environment* 955 (2024): 177059.

[22] *See* Wu, Yonghao, et al. "Outdoor light at night, air pollution, and risk of cerebrovascular disease: a cohort study in China." *Stroke* 55.4 (2024): 990-998.

[23] *See* Menculini, Giulia, et al. "Insights into the Effect of Light Pollution on Mental Health: Focus on Affective Disorders—A Narrative Review." *Brain Sciences* 14.8 (2024): 802.

[24] *See, e.g.,* Yang, Le, et al. "Association between outdoor artificial light at night, circadian health, and LDL-C in intracranial artery atherosclerotic stenosis." *Clinical Epigenetics* 17.1 (2025): 132.

specific wavelengths and employ cross-sectional designs. Studies with these designs may show a correlation but cannot prove causation because they do not establish a clear time order (i.e., whether the exposure came before or after the health outcome) and do not control for other unmeasured factors over time that could otherwise explain the association. Referenced studies using wrist-[25] or chest-worn[26] light sensors similarly fail to capture blue wavelength LED light exposure at the ocular level. These sensors measure total ambient illuminance at specific location of the body surface, which may be affected by factors such as body position, movement, or clothing occlusion. The measured exposure of these sensors may diverge significantly from true ocular light exposure, i.e., the specific wavelengths and intensities of light reaching the retina, which may vary based on factors such as direction the eyes are pointing, eyelid state, pupil size, and what is directly in the line of sight. The referenced research on blue wavelength LED light and retinal injury relied on non-human models and in vitro systems under extreme, non-physiological exposure conditions, and without considering the human natural aversion response to bright light, which cannot be directly extrapolated to typical human exposures, and acute photochemical retinal damage from blue wavelength LED products under normal conditions of use remains undemonstrated in humans.[27]

For pulsed LED lights (e.g., flashing lights), as noted in FDA's response in May 2024 to a citizen petition submitted by Soft Lights Foundation under docket number FDA-2023-P-0233 (the "2024 response"),[28] FDA is aware that some evidence suggests that individuals associate health effects, like migraines, with temporal light modulation. However, as noted in our 2024 response, at that time there was insufficient evidence (e.g., medical studies of the health impacts of flicker from LED lights) on contributing factors, affected populations, conditions, and product characteristics posing risks,[29] and FDA is not aware of any new evidence addressing these insufficiencies (including the studies referenced in your petition attachments) that would support a finding that FDA needs to initiate a study to determine the necessity for the development of standards for use for LED products at this time. The submitted studies either lack LED-specific

[25] *See* Windred, Daniel P., et al. "Personal night light exposure predicts incidence of cardiovascular diseases in> 88,000 individuals." *medRxiv* (2025): 2025-06; Burns, Angus C., et al. "Day and night light exposure are associated with psychiatric disorders: an objective light study in> 85,000 people." *Nature Mental Health* 1.11 (2023): 853-862.
[26] *See, e.g.,* Ding, Wenqin, et al. "Personal 24-hour light exposure pattern with obesity and adiposity-related parameters in school-aged children: a cross-sectional study based on compositional data analysis." *Environmental Research* 275 (2025): 121422.
[27] *See, e.g.,* Françon, Anaïs et al. "The blue light hazard and its use on the evaluation of photochemical risk for domestic lighting. An in vivo study." *Environment International* 184 (2024): 108471*;* Li, Xuan, et al. "Blue light pollution causes retinal damage and degeneration by inducing ferroptosis." *Journal of Photochemistry and Photobiology B: Biology* 238 (2023): 112617; Hiramoto, Keiichi, et al. "Induction of skin cancer by long-term blue light irradiation." *Biomedicines* 11.8 (2023): 2321; Nakamura, Maho, et al. "Exposure to excessive blue LED light damages retinal pigment epithelium and photoreceptors of pigmented mice." *Experimental eye research* 177 (2018): 1-11. As noted in our 2024 response, the Agency was aware of only two case studies of photochemical retinal injuries, both of which were caused by atypical exposure to blue-rich LED lights (i.e., staring directly into or repeated exposure to the light source), which has not changed since that time.
[28] The citizen petition (Docket #FDA-2023-P-0233) and FDA's 2024 response are available at https://www.regulations.gov/ using the petition docket number.
[29] *See* FDA's 2024 response at 15.

analysis,[30] rely on exposure conditions not representative of real-world use, [31] or do not establish dose-response relationships linking specific LED product characteristics to specific adverse health outcomes in humans under realistic conditions. Furthermore, several studies examine stroboscopic lighting in extreme contexts – such as entertainment venues,[32] digital media displayed on virtual reality headsets,[33] or torture environments[34] – that are not generalizable to general-purpose LED lighting products.

The referenced research on white LED light and retinal injury shares some of the same limitations as the studies on retinal injury from blue wavelength LED light, namely a reliance on non-human models and in vitro systems under extreme, non-physiological exposure conditions without accounting for the human natural aversion response to bright light, and these findings cannot be directly extrapolated to typical human exposures.[35] The referenced studies regarding glare are either not specifically related to LED light,[36] or do not discuss or identify public safety concerns.[37]

Taken together, the referenced literature does not provide sufficient quality or consistency of evidence to support an FDA finding that it is necessary to initiate a study to determine the necessity for the development of standards of use for LED products and submit a report to Congress at this time.

In sum, based on the lack of evidence that has come to FDA's attention about changes in current technology, the absence of information providing sufficiently clear and strong evidence that LED products pose a risk to public health and safety (including from ARO and other information submitted to the Agency), and the shortcomings of the peer-reviewed literature referenced in

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[30] *See* Windred, Daniel P., et al. "Personal night light exposure predicts incidence of cardiovascular diseases in> 88,000 individuals." *medRxiv* (2025): 2025-06; Palomar-Cros, Anna, et al. "Indoor and outdoor artificial light-at-night (ALAN) and cancer risk: a systematic review and meta-analysis of multiple cancer sites and with a critical appraisal of exposure assessment." *Science of The Total Environment* 955 (2024): 177059.

[31] *See* Bullough, J., Skinner, N., & Rea, M., "Impacts of Flashing Emergency Lights and Vehicle-Mounted Illumination on Driver Visibility and Glare," *SAE Technical Paper* 2019-01-0847; Jaadane, Imene, et al. "Retinal damage induced by commercial light emitting diodes (LEDs)." *Free Radical Biology and Medicine* 84 (2015): 373-384; Shang, Yu-Man, et al. "Light-emitting-diode induced retinal damage and its wavelength dependency in vivo." *International journal of ophthalmology* 10.2 (2017): 191.

[32] *See* Salet, Newel, et al. "Stroboscopic light effects during electronic dance music festivals and photosensitive epilepsy: a cohort study and case report." *BMJ open* 9.6 (2019): e023442.

[33] *See* Jordan, J. Bern, and Gregg C. Vanderheiden. "International guidelines for photosensitive epilepsy: gap analysis and recommendations." *ACM transactions on accessible computing* 17.3 (2024): 1-35.

[34] *See* Leach J. "Psychological factors in exceptional, extreme and torturous environments." *Extreme Physiology & Medicine* 2016 Jun 1;5:7.

[35] *See. e.g.,* Jaadane, Imene, et al. "Effects of white light-emitting diode (LED) exposure on retinal pigment epithelium in vivo." *Journal of cellular and molecular medicine* 21.12 (2017): 3453-3466.

[36] *See, e.g.*, Watanabe, Brooke L., et al. "Is use of warning lights and sirens associated with increased risk of ambulance crashes? A contemporary analysis using National EMS Information System (NEMSIS) data." *Annals of emergency medicine* 74.1 (2019): 101-109.

37 Abboushi, Belal, et al. "The position index of overhead LED sources under different spectral power distributions and background luminances." *Leukos* 21.1 (2025): 65-82.

your petition attachments—and consistent with the results of the 2023 literature search on the health effects of LED products—FDA has not found that a study and report to Congress about the effects of LED products pursuant to section 533(a)(2) of the FD&C Act are necessary at this time.

Finally, at this time, taking into account the broad scope and overall workload of the Agency, as well as the numerous ongoing activities FDA is conducting as required by the Radiation Control provisions, FDA believes it is in the best interest of the public health to focus the Agency's resources on other radiological health priorities such as removing defective or non-compliant products from the market to ensure public safety. Pursuant to 21 CFR 10.30(e)(1), the Commissioner shall rule upon each petition "taking into consideration (i) available agency resources for the category of subject matter, (ii) the priority assigned to the petition considering both the category of subject matter involved and the overall work of the agency, and (iii) time requirements established by statute." For the reasons discussed above, your petition has not shown that the requested study and report to Congress regarding LED products warrant use of the Agency's limited resources at this time.

IV. Conclusion

For the reasons set forth above, and in accordance with 21 CFR 10.30(e), FDA denies your request that FDA initiate a study and submit a report to Congress on the photobiological, neurological, psychological, hormonal, and other health hazards of LED products, the measures necessary to assure the comfort, health, safety, and civil rights of the public from the hazards of LED Visible Light radiation, and the cooperation needed between FDA and other federal agencies to implement a "properly functioning radiation control program" for LED products. FDA continues to monitor impacts to public health and safety from radiation-emitting products consistent with our jurisdiction.
If you have any questions about this response, please contact CDRHPetitions@fda.hhs.gov.

Sincerely,

ELLEN J. FLANNERY -S

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Ellen J. Flannery, J.D.
Deputy Center Director for Policy
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