Soft Lights Foundation

9450 SW Gemini Drive
PMB 44671
Beaverton, OR 97008

May 29, 2025

BY EMAIL

Robert F. Kennedy, Jr., Secretary
Health and Human Services
policy@mahatransition.org

Re: MAHA – FDA Regulation of LED Products

Dear Secretary Kennedy,

I am writing to you in regards to the 73-page, May 22, 2025, MAHA report which was highlighted by Inside Lighting Magazine (https://inside.lighting/news/25-05/lightings-health-impact-gains-national-recognition). Beginning on page 50 of the MAHA report is a discussion of the adverse impacts of artificial light on human health and well-being. This is an area of expertise of the Soft Lights Foundation.

Congress gave the US Food and Drug Administration the responsibility of protecting public health from the hazards of electromagnetic radiation from electronic products, including visible light. 21 U.S. Code Chapter 9 Subchapter V Part C - Electronic Product Radiation Control, 21 U.S.C. 360hh – 21 U.S.C. 360ss, contains the statutes for electronic product radiation control programs for everything from television sets to microwave ovens, to cell towers, to LED vehicle headlights. The department within the FDA that is tasked with carrying out these radiation control programs is the Center for Devices and Radiological Health ("CDRH").

The issue is that the FDA long ago abandoned all work within the CDRH to test, evaluate, and regulate electromagnetic radiation to instead focus solely on medical devices. 21 U.S.C. 360kk(f) establishes a Technical Electronic Product Radiation Safety Standards Committee ("TEPRSSC") to assist the FDA with establishing performance standards for electronic products that emit electromagnetic radiation. However, the FDA has essentially dissolved TEPRSSC, with the last meeting having occurred in 2016 and only one meeting having occurred in the past two decades.

21 U.S.C. 360ii(a)(6)(A) requires the FDA to establish and maintain a liaison with each federal agency to test and evaluate electronic products to control unnecessary electromagnetic radiation to protect public health and safety. The FDA has chosen to ignore this mandate and has not established a liaison with any federal agency, including NHTSA, OSHA, EPA, DOE, Access Board, CPSC, FAA or any other federal agency.

The primary focus of the Soft Lights Foundation is the adverse health impacts of the visible light emitted by Light Emitting Diodes ("LEDs"). Because the FDA has essentially dissolved TEPRSSC and because the FDA has no resources devoted to compliance with 21 U.S.C. 360ii, there are currently no performance standards for any LED product. This means that there are no performance standards to protect human health, safety, or civil rights for LED vehicle headlights, LED streetlights, LED General Service Lamps, LED flashing lights on police cars, LED indicator lights on washing machines, or LED lights on aircraft.

The FDA has received thousands of reports of harm from exposure to LED light but has failed to act on any of those reports. The Soft Lights Foundation submitted multiple federal regulatory petitions to the FDA to comply with 21 U.S.C. 360ii. The FDA hired a secret outside agency to review and deny the petitions. It is unknown if this secret outside agency is even qualified to review information on the adverse impacts of LED light. The MAHA report states, "The purpose of this report is radical transparency about our current state…", so the use of a secret outside agency to review reports of harm from exposure to LED light is contrary to MAHA's mission.

To compel the FDA to restore TEPRSSC and comply with 21 U.S.C. 360ii, I filed a Pro Se lawsuit against the FDA and NHTSA to compel the two agencies to establish and maintain a liaison to test and evaluate LED vehicle headlights. The FDA, through the US DOJ, is fighting this lawsuit and is attempting to have the case dismissed. These actions are contrary to MAHA's mission.

The issue of blinding LED vehicle headlights is the most prominent issue, with LED headlights impacting the lives of 300,000,000+ Americans. Media articles about blinding LED headlights appear once or twice a month. On May 22, 2025, US House Representative Marie Gluesenkamp Perez became the first member of Congress to address the issue of blinding LED headlights in a speech to the House Transportation and Infrastructure Committee. (https://x.com/RepMGP/status/1925241813352202334).

The FDA is required under 21 U.S.C. 360ii to collaborate with NHTSA to establish the performance standards for LED headlights but has failed to do so. The FDA is also required to collaborate with the EPA to limit light pollution, since light pollution is another term for unnecessary electromagnetic radiation in the visible light part of the spectrum. The FDA is required to collaborate with the Department of Energy on standards for General Service Lamps and streetlights. The FDA is required to collaborate with the FAA to establish standards for LED lights on towers and on aircraft. The FDA is required to collaborate with the CPSC to set standards to protect children from toys with LED lights. The FDA is required to collaborate with the Access Board to ensure that LED lights do not create discriminatory barriers. The FDA has chosen to ignore all these requirements and issues.

The Soft Lights Foundation respectfully requests that the Secretary of HHS take the following actions in conjunction with the May 20, 2025 MAHA report:

1. Direct the FDA to drop their opposition to my lawsuits and agree to settle.

2. Direct the FDA to comply with 21 U.S.C. 360ii(a)(6)(A) and establish and maintain a liaison with each federal agency to test, evaluate, and publish performance standards for LED products, including LED vehicle headlights, LED flashing lights on police cars, LED General Service Lamps, LED streetlights, LED displays, LEDs in children's toys, and light pollution.
3. Direct the FDA to restore TEPRSSC and modify the TEPRSSC Charter to have TEPRSSC meet quarterly.
4. Direct the FDA to divide the CDRH into two separate departments: A) Center for Medical Devices and B) Center for Radiological Health.

The Soft Lights Foundation has extensive technical expertise on nearly all aspects of LEDs and we offer to assist the Secretary and the FDA meet MAHA goals.

Sincerely,

/s/ Mark Baker
President
Soft Lights Foundation
mbaker@softlights.org