Soft Lights Foundation

9450 SW Gemini Drive
PMB 44671
Beaverton, OR 97008

November 19, 2024

BY EMAIL

Bernie Sanders, Chair
US Senate Committee on Health, Education, Labor, & Pensions
billy_gendell@sanders.senate.gov

Re: Corruption at the FDA CDRH

Dear Senator Sanders,

The Soft Lights Foundation is a 501(c)(3) nonprofit that advocates for the protection of individuals and the environment from the harms of LED lights. We have communicated extensively with the US Food and Drug Administration Center for Devices and Radiological Health over the past several years. The FDA CDRH was mandated by Congress in the 1968 Radiation Control for Health and Safety Act to minimize the exposure to, and emissions of, unnecessary electromagnetic radiation from electronic products. The Soft Lights Foundation has discovered through our communications that the FDA CDRH has made a conscious and willful decision to unlawfully abandon all efforts to test, evaluate, and regulate electromagnetic radiation from non-medical products.

TEPRSSC

Congress created the Technical Electronic Product Radiation Safety Standards Committee to review information on electromagnetic radiation and propose performance standards to the FDA Commissioner. Jeffrey Shuren was the Director of the FDA CDRH for 14 years until his retirement in July 2024. During his time as Director, Mr. Shuren unlawfully dissolved TEPRSSC so that no recommendations could be made to the FDA Commissioner for performance standards for cell phone towers, cell phones, WiFi routers, Smart Meters, LED vehicle headlights, LED streetlights, LED lightbulbs, or LED flashing lights on emergency vehicles. This dissolution of TEPRSSC has allowed companies to manufacture and sell these products with little or no regulations to protect public health and safety.

Electronic Product Radiation Control

21 U.S.C. Part C establishes requirements for the FDA CDRH to implement an Electronic Product Radiation Control program for researching, testing, evaluating, and studying electromagnetic radiation from electronic products, and for collaborating with other federal agencies such as NHTSA, DOE, EPA, OSHA, Access Board and others to develop and publish performance standards to protect public health. During his tenure, Mr. Shuren stopped all work involving the Radiation Control Program for non-medical products. There has thus been no collaboration with NHTSA to set limits for LED vehicle headlights, no

collaboration with EPA to set limits on light pollution, and no collaboration with OSHA to set limits on LED flashing lights for first responders.

Regulatory Petitions

The Soft Lights Foundation submitted four regulatory petitions to the FDA CDRH requesting that the FDA CDRH publish performance standards for LED products. This process would normally entail having the TEPRSSC review information on LEDs and provide a report to the FDA Commissioner and Congress. The meetings of the TEPRSSC are required to be made publicly available. Instead of using TEPRSSC, the FDA CDRH used a secret outside agency to review the Soft Lights Foundation petitions. The FDA denied all four Soft Lights Foundation petitions based on the work of this secret organization.

Freedom of Information Act

The Soft Lights Foundation submitted a FOIA to the FDA CDRH for all documents related to testing, evaluating, researching, and publishing performance standards for LED products. After a two and half year wait, the FDA provided a single document to the Soft Lights Foundation, which was the FDA CDRH's own denial of the Soft Lights Foundation petitions. The FDA CDRH provided no other documents, which is an unlawful withholding of documents in violation of the FOIA request.

LED Incident Reports

Because the FDA CDRH refuses to comply with the law, the Soft Lights Foundation began collecting reports of harm from exposure to LED Visible Light radiation. Over 150 reports have been submitted since April 2024. (https://www.softlights.org/led-incident-reports/). In addition, the Soft Lights Foundation has collected over 60,000 signatures and comments on a public petition to ban blinding LED headlights. The Soft Lights Foundation submits these reports to the FDA CDRH monthly, but the FDA CDRH has not notified Congress or the public about LED hazards and has not established a liaison with any other federal agency.

Lawsuits

Mark Baker, President of the Soft Lights Foundation, filed a lawsuit against the FDA CDRH in January 2024, to compel the FDA to implement the Electronic Radiation Control programs for LED products. The FDA, via the DOJ, is fighting this lawsuit. Mr. Baker filed a second lawsuit against the FDA and NHTSA for failing to maintain a liaison to test and evaluate LED vehicle headlights, as required by 21 U.S.C. 360ii(a)(6)(A), in September, 2024.

The FDA CDRH is a rogue agency, deliberately ignoring Congressional mandates to implement a Radiation Control Program for LED products, willfully denying the public access to information, and purposely dissolving TEPRSSC to ensure that LED products are never regulated. FDA Commissioner Robert Califf, and Secretary of Health of Human Services Xavier Becerra are fully aware of this situation and allow the situation to continue without intervention.

The Soft Lights Foundation respectfully requests that the US Senate Committee on Health, Education, Labor, & Pensions address this extraordinarily serious matter during the confirmation process for Secretary of Health and Human Services and that the Committee open a Senate investigation into the FDA CDRH's unlawful behavior.

Sincerely,

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