Soft Lights Foundation

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June 16, 2024

BY EMAIL

Christi Grimm, Inspector General
Office of Inspector General, Health and Human Services
public.affairs@oig.hhs.gov

Re: Investigation of FDA CDRH Director Jeffrey Shuren

Dear Christi Grimm,

Jeffrey Shuren has been the Director of the Food and Drug Administration Center for Devices and Radiological Health since 2009. It has been under Mr. Shuren's Directorship that Light Emitting Diode products have been allowed to explode into the environment nearly everywhere without any oversight by the FDA. It is my assertion that Mr. Shuren has acted willfully and recklessly to prevent FDA regulation of LED products, as required by 21 U.S.C. 360ii.

On May 24, 2024, the FDA CDRH denied all four Soft Lights Foundation petitions to regulate LED products.[1] In the rejection letter, the FDA asserts that the Soft Lights Foundation did provide incontrovertible proof that LED Visible Light radiation is causing harm, and therefore the FDA is not required to issue performance standards for LED products. However, in issuing its decision to not regulate any LED product, the FDA has acted unilaterally, without consulting with any other federal agency, and thus the FDA CDRH's and Mr. Shuren's actions are illegal.

21 U.S.C. 360ii(a)(6) states:

> *[The Secretary 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 (A) techniques, equipment, and programs for testing and evaluating electronic product radiation, and (B) the development of performance standards pursuant to section 360kk of this title to control such radiation emissions.*

As is clearly stated in this statute, the FDA CDRH is required to "consult and maintain liaison" with federal agencies such as NHTSA, OSHA, FAA, Access Board, DOE, CPSC, EPA, FHWA and other federal agencies to develop performance standards for LED products. Because the Soft Lights Foundation has been notifying Mr. Shuren for many years regarding the FDA's duty to comply with 21

[1] 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

U.S.C. 360ii and the FDA's duty to protect public health and safety, Mr. Shuren's decision to not consult or liaise with other federal agencies is surely willful, and not a mere oversight.

The results of Mr. Shuren's illegal actions are that NHTSA cannot publish performance standards for LED vehicle headlights, the DOE cannot publish performance standards for LED General Service Lamps, OSHA cannot publish safety standards for workers exposed to LED flashing lights, and the Access Board cannot publish guidelines to ensure disability access involving LED products. Because Mr. Shuren's actions are willful and reckless, and not merely an oversight, we are requesting an investigation by the HHS OIG.

Sincerely,

/s/ Mark Baker
President
Soft Lights Foundation
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