

July 3, 2023

BY EMAIL

Michael Backstrom, Vice President, Regulatory Affairs Southern California Edison michael.backstrom@sce.com

Re: LED Streetlights Lack FDA Approval

Dear Michael Backstrom,

An LED streetlight is an electronic product which is regulated by the US Food and Drug Administration. The FDA presentation "How to Get Your Electronic Product on the U.S. Market" details the authority of the FDA to regulate the radiation from electronic products and the requirements of manufacturers to receive FDA approval for their electronic products that emit radiation.¹

SCE has chosen to install LED streetlights in numerous municipalities. However, the FDA has not approved any LED streetlight products to ensure the comfort, health, and safety of the public. The FDA is mandated by the 1968 Radiation Control for Health and Safety Act (21 U.S.C. 360ii) to publish performance standards for electronic products that emit radiation, and yet the FDA has failed to comply with 21 U.S.C. 360ii for LED products, including LED streetlights.

LED streetlights are a human health hazard which have been documented to cause seizures, migraines, anxiety, and eye injury. In addition, artificial light at night has been documented to cause significant increases in risk for mood disorders, diabetes, heart disease, breast cancer, and early mortality. The contact person at the FDA is Robert Ochs, Director, FDA Center for Devices and Radiological Health, OHT8 (robert.ochs@fda.hhs.gov).

It is negligent for a company to install and operate an electronic product that has no FDA approval, and which is known to put the public at risk of harm. To protect the public from LED visible radiation, LED streetlights must not be operated in public spaces. To recover expenses related to the removal of any existing LED streetlights, the Soft Lights Foundation recommends that SCE sue the FDA and the DOE for failing to comply with 21 U.S.C 360ii and publish the required performance standards for LED streetlights and for failing to disclose to SCE that LED products are a human health hazard.

In any case, SCE cannot continue to install or operate LED streetlights knowing that the LED streetlights have not been FDA approved and knowing that the LED streetlights are causing serious adverse health impacts and creating discriminatory barriers for citizens.

¹ <u>https://www.fda.gov/media/88417/download</u>

Sincerely,

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