



9450 SW Gemini Drive
PMB 44671
Beaverton, OR 97008

July 1, 2024

BY EMAIL

William Winne, Agency Counsel
Federal Highway Administration
William.Winne@dot.gov

Re: Request for Compliance with 21 U.S.C. 360ii(a)

Dear William Winne,

21 U.S.C. 360ii(a) directs the US Food and Drug Administration to, "minimize the emissions of and the exposure of people to, unnecessary electronic product radiation [and] consult and maintain liaison with ... other appropriate Federal departments and agencies on ... the development of performance standards..."

Much of the Visible Light radiation emitted by Light Emitting Diodes is unnecessary electronic product radiation. An example is an LED Rectangular Rapid Flashing Beacon that rapidly pulses high-radiance digital light that can cause non-epileptic and epileptic seizures. Therefore, 21 U.S.C. 360ii(a) requires the FDA and FHWA to consult and liaise to develop performance standards for LED products so as to minimize the emissions of, and exposure to, unnecessary Visible Light electromagnetic radiation. Presently, both the FDA and FHWA are in violation of 21 U.S.C. 360ii(a).

The Soft Lights Foundation requests that FHWA contact the Director of the FDA Center for Devices and Radiological Health, Jeffrey Shuren (jeff.shuren@fda.hhs.gov) to correct the 21 U.S.C. 360ii(a) violation and initiate the development of performance standards for LED products.

Sincerely,

/s/ Mark Baker
President

Soft Lights Foundation
mbaker@softlights.org