May 19, 2024

Complaint Submitted to US Health and Human Services Office for Human Research Protections via Webform (https://oashsps.my.site.com/ohrpwebforms/s/complaint-web-form).

The FDA CDRH has not complied with 21 U.S.C. 360ii and has not vetted or approved any product using Light Emitting Diodes that emits LED Visible Light radiation. Yet, utility companies, automotive companies, lighting companies and have others have flooded the environment with LED devices which have been demonstrated to cause serious adverse health effects such as non-epileptic and epileptic seizures, migraines, panic attacks, anxiety, mood disorders, increased risk of disease, and photobiological harm. The result is a massive real-world experiment that is unsupervised and uncontrolled.

This complaint is about the lack of supervision by the FDA CDRH over this real-world LED study. Rather than vetting LED Visible Light radiation in controlled experiments and then publishing performance standards to ensure photobiological, hormonal, neurological, and psychological safety, the FDA CDRH has allowed LED products to enter into the environment in an uncontrolled and unsupervised experiment, with the FDA CDRH not even collecting data on the impacts of LED products on the real-world participants.

Submitted by:

Soft Lights Foundation