U.S. Department of Health and Human Services
Office of Inspector General

Requesting information about your complaint

Every report we receive is important, however, not every submission results in an investigation.

Once submitted, we will review your complaint for relevance and completeness. If you have identified yourself, a reviewing official may contact you for further information. It is important to note that you might not be contacted by an investigator but that does not mean your complaint is not being investigated. Due to the high volume of complaints we receive, it is not possible to contact every complainant. The Hotline will not be able to confirm receipt of your complaint or respond to any inquiries about action taken on your complaint.

You may request information about your complaint through the OIG Freedom of Information Act officer (https://oig.hhs.gov/foia). Remember to phrase your request in terms of a search for records pertinent to your complaint, not status. You should wait at least six months before filing such a request.

Your complaint summary

Before you submit, make sure you check your information and save or print a copy for your records.

Allegation details

Allegation type

Gross misconduct

Program
Food & Drug Administration (FDA)

Business unit
FDA-Other

Office name
Center for Devices and Radiological Health

Date of activity
6/12/2022

Is the activity still happening?
Yes

Complaint history

Previously reported
Yes

Previously reported to
Management

Date previously reported
6/12/2022

Subject information

Subject

Type of subject
Individual

Full name

Jeffrey Shuren

Alias/Nickname
-

Date of birth
-

Physical description
-

Relationship to subject
Other: None

Contact details

Home phone
-

Cell phone
-

Work phone
301-796-5900

Personal email
-

Work email
jeff.shuren@fda.hhs.gov

Home address
-

Employer information

Job title

Center Director

Employer
FDA

Employer address
-

Employer phone
-

Witness information

Your narrative

Your description of events

Jeffrey Shuren has been the Director of the FDA CDRH for 13 years, which is during the entire time that Light Emitting Diode products were being released into the environment. 21 U.S.C. 360ii mandates that the FDA publish performance standards for electromagnetic radiation emitted by electronic products. For example, the FDA has published performance standards for laser products.
I assert that Mr. Shuren made the reckless and negligent decision to direct his staff to not publish performance standards for Light Emitting Diode products in deference to the LED lighting industry. For 13 years now, the LED lighting industry has made billions of dollars selling unvetted and unregulated LED products because Mr. Shuren has consciously and knowingly allowed this to happen without FDA oversight.
On June 12, 2022, the Soft Lights Foundation submitted petition FDA-2022-P-1151 to compel Mr. Shuren to publish these mandated performance standards. Mr. Shuren is sitting on the petition and taking no action.
The harm caused by Mr. Shuren is nearly incalculable. LED visible radiation is a human health and ecosystem hazard. LED streetlights, for example, greatly increase light pollution versus non-LED versions, because the FDA did not collaborate with the DOE to publish restrictions on peak luminance or blue wavelength, in violation of 21 U.S.C. 360ii. LED strobe lights are causing seizures, migraines, panic attacks, and eye injury because the FDA has not placed any restrictions on the

luminance or digital flash characteristics.
During the Trump administration, Mr. Shuren published on the FDA's website in the laser section that the laser section does not include LEDs. However, Mr. Shuren did not publish a section on LEDs. At least as far back as 2016, internal FDA presentations show that FDA staff had concerns about LED visible radiation, and yet Mr. Shuren directed them to take no action.
There may be other forces involved. It is possible that Mr. Shuren's bosses are the ones who directed Mr. Shuren to support the LED lighting industry and ignore public health and safety, but Mr. Shuren has been Director for 13 years, through multiple political administrations, so the evidence that I have seen leads me to believe that Mr. Shuren has been acting on his own.
21 C.F.R. Part 1040 contains the sections for regulating visible radiation from light emitting products. 1040.10 is for lasers, 1040.20 is for sunlamp products. 1040.30 is for mercury vapor. It has been Mr. Shuren's decision to not publish 1040.40 for LEDs.
I have requested FOIA documents from the FDA, but they refuse to provide anything. Upon further pushing by me, the FDA told that there is at least a 2 year delay. I suspect that this is more about a conspiracy than it is an actual delay in finding the records. I believe that these records will show that FDA staff raised the issue of regulating LED products, but that Mr. Shuren directed staff not to act.
Because of Mr. Shuren's actions, we are now looking at having to recall all vehicles with LED headlights, remove all LED streetlights, eliminate the federal ban on the incandescent light bulb, redo all the grocery stores that have installed LED lighting, and suffer through countless lawsuits as the law firms begin to hold officials accountable.
I ask that the FDA OIG hold Mr. Shuren responsible for his actions, remove him from his position at the FDA, and notify the FDA that they are mandated to publish performance standards for LED products.

Attached files

23-0023AA FOIA Appeal.pdf, FDA Signed Response Letter To Mark Baker.pdf, FDA-2022-P-1151 Request for Interviews.pdf, FDA Petition to Regulate LEDs.pdf, One Year After Petition.pdf, 2022-8833 Baker const denial appeal RESPONSE (1).pdf, Petition to Regulate LED Strobe Lights.pdf, Center for Radiological Health Proposal.pdf, Combined DOE Petition.pdf, Soft Lights Mail - Resignation of Jeffrey Shuren.pdf

---

Evidence description

-

Your information

Your consent to disclose

No restrictions. Confidentiality and anonymity is not requested. If necessary, you may contact me for additional information and there are no restrictions on the release of my contact information.

Name

Mark Baker

Date of birth

-

Medicare number

-

Medicaid number

-

Social Security Number (SSN)

-

Your contact details

Home phone

-

Cell phone

-

Work phone

234-206-1977

Personal email

-

Work email

mbaker@softlights.org

Your home address

9450 SW Gemini Drive, PMB 44671
Beaverton, OR 97008

Your employment information

HHS employee, contractor, or grantee

No