March 31, 2023

[redacted]

Dear [redacted]:

Thank you for your March 14, 2023, email to HHS Secretary Becerra regarding your concerns relating to LED lights. Your correspondence has been referred to FDA's Center for Devices and Radiological Health (CDRH) for response.

In your correspondence you refer to the Soft Lights Foundation citizen petition to FDA (petition), which we are interpreting to mean Docket Number FDA-2022-P-1151 requesting that FDA "issue 21 CFR Part 1040.40 to regulate electromagnetic radiation in the visible portion of the spectrum emitted by products that use Light Emitting Diodes and that these regulations set restrictions on spatial non-uniformity, chip-level peak luminance and peak radiance, spectral power distribution, and square wave flicker and that the regulations be designed to protect the physical and psychological health, safety, comfort, and civil rights of those who are negatively impacted by LED light."[1]

As noted in FDA's interim response to the petition dated November 6, 2022, FDA has been unable to reach a decision on the petition because it raises issues requiring further review and analysis by agency officials. Please be assured that we are working diligently and considering carefully the scientific and other information that has been submitted in the petition, as well as other information submitted to the public docket.

If you have information that you would like FDA to consider during its review of the petition, you may submit a comment to the public docket for the petition on Regulations.gov (https://www.regulations.gov/document/FDA-2022-P-1151-0001). Thank you for your interest in this matter.

Sincerely,

Robert Ochs

Robert Ochs, Ph.D.
Director
Office of Health Technology 8 (OHT 8: Radiological Health)
Center for Devices and Radiological Health

[1] Soft Lights Foundation filed a second citizen petition on January 22, 2023, FDA-2023-P-0233, requesting that FDA "issue 21 CFR Part 1040.41 to regulate electromagnetic radiation in the visible portion of the spectrum emitted by products that use Light Emitting Diodes that pulse, flash, or strobe, and that these regulations set restrictions on spatial non-uniformity, chip-level peak luminance and peak radiance, spectral power distribution, synchronous and asynchronous flash rates, and rise and decay characteristics, and that the regulations be designed to protect the physical and psychological health, safety, comfort, and civil rights of those who are negatively impacted by LED strobe lights."