U.S. FOOD & DRUG ADMINISTRATION

June 30, 2023

Mark Baker, President
Soft Lights Foundation
9450 SW Gemini Drive PMB 44671
Beaverton, OR 97008

Sent via email to: mbaker@softlights.org

Re: Citizen Petition – Docket Number FDA-2023-P-0233

Dear Mr. Baker:

This is an interim response to the petition dated January 22, 2023, filed by the Food and Drug Administration (FDA) on January 23, 2023. In the petition, you requested 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.

FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA regulations on citizen's petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions about this interim response, please contact Patricia Kaufman of our Office of Policy at 301-796-1174.

Sincerely yours,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2023.06.30 12:27:26 -04'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health

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