U.S. FOOD & DRUG ADMINISTRATION

November 6, 2022

Mark Baker, President
[redacted]

Sent via email to: [redacted]

Re: Citizen Petition – Docket Number FDA-2022-P-1151

Dear Mr. Baker:

This is an interim response to the petition dated June 13, 2022, filed by the Food and Drug Administration (FDA) on June 13, 2022. In the petition, you requested 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 (LED) and that the regulation set restrictions on spatial non-uniformity, chip-level peak luminance and peak radiance, spectral power distribution, and square wave flicker to protect the physical and psychological health, safety, comfort, and civil rights of those who are negatively impacted by LED light.

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: 2022.11.06 16:15:34 -05'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
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