U.S. FOOD & DRUG ADMINISTRATION

January 17, 2023

Mark Baker, President
Soft Lights Foundation
9450 SW Gemini Drive PMB 44671
Beaverton, OR 97008
mbaker@softlights.org

Dear Mr. Baker:

Thank you for your December 30, 2022, email to HHS Secretary Becerra regarding your pending citizen petition (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." Your correspondence has been referred to FDA's Center for Devices and Radiological Health (CDRH) for response.

As you are aware, the citizen petition process is described in FDA regulations in 21 CFR 10.30. This process is designed to assure transparency through a public process. Citizen petitions are made publicly available, and a public docket is established to allow members of the public to review and comment on the information submitted in the citizen petition and on other public comments included in the docket.

When you submitted your citizen petition, you certified that the written petition "includes all information and views on which the petition relies," as required by 21 CFR 10.30(b)(3). Your organization has also submitted additional information in comments to the public docket. We are not granting your request for a meeting to discuss your citizen petition at this time because it is not CDRH's practice to meet with petitioners while their petition is pending. This helps ensure that the information relevant to the petition resides in the public docket, which provides transparency and an adequate opportunity for comment by interested parties.

FDA provided an interim response to your citizen petition dated November 6, 2022, in accordance with the regulations, 21 CFR 10.30(e)(2)(iv). Our interim response informed you that FDA has been unable to reach a decision on your 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 you have submitted in your citizen petition, as well as other information submitted to the public docket.

Thank you for your interest in this matter.

Sincerely,

Robert Ochs, Ph.D.
Director
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health