Soft Lights Foundation

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BY EMAIL

Patricia Kaufman, Regulatory Counsel, CDRH
Food and Drug Administration
patricia.kaufman@fda.hhs.gov

Re: Petition FDA-2022-P-1151 Request for Explanation of Delay

Dear Patricia Kaufman,

On June 12, 2022, the Soft Lights Foundation submitted citizen petition FDA-2022-P-1151 to the FDA to publish performance standards for LED products. On November 6, 2022, the FDA responded that, "*FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials*."

21 CFR 10.30(e)(2)(i) through (iv) states that the FDA shall either approve the petition, deny the petition, dismiss the petition or "*Provide a tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information*" within 180 days of the submission of the petition. The FDA's November 6, 2022 letter to the Soft Lights Foundation stated only that the petition "raises issues", but did not detail what those issue are, why those issues prevented a ruling, or how long the analysis would take to complete. 21 CFR 10.30(e)(2)(iv) provides some examples of how the FDA may respond, but does not restrict responses to limited information, nor does the statute authorize a response that lacks detailed information to ensure transparency. The November 6, 2022, response lacks transparency and detail and, now that the petition has been in the hands of the FDA for approximately 350 days, is entirely insufficient.

On May 24, 2023, Americans for Responsible Technology submitted a similar petition, demanding that the FDA comply with the 1968 Radiation Control for Health and Safety Act and study and take action to minimize risk from exposure to non-ionizing electromagnetic radiation.[1] This petition by ART is similar to the Soft Lights Foundation petition, but references all non-ionizing electromagnetic radiation, not just the visible radiation emitted by LEDs. The FDA now has two petitions which make similar requests.

The FDA is not authorized to simply sit on petitions and ignore them. The FDA is not authorized to simply ignore the adverse impacts of non-ionizing radiation. The FDA is required to protect the

[1] https://www.americansforresponsibletech.org/_files/ugd/2cea04_e1e8715fdb41466caaf767e16c16522f.pdf

comfort, health, and safety of the public. Therefore, as per 21 CFR 10.30(e)(2)(iv), the Soft Lights Foundation hereby requests the following responses from the FDA:

1) Detailed explanation of each of the "issues" that have been raised by petition FDA-2022-P-1151.
2) Summary of what the FDA understands about:
    a) Spatial non-uniformity of non-point source emitters such as LEDs.
    b) Peak luminance.
    c) Lack of inverse square law dispersion from LEDs.
    d) Spectral power distribution.
    e) Hazards of 450nm blue wavelength light.
    f) Square wave flicker.
    g) Pulsed visible radiation such as LED strobe lights.
3) Summary of what the FDA understands about its mandate to regulate:
    a) LED vehicle headlights
    b) LED strobe lights
    c) LED General Service Lamps
    d) LED indicator lights such as in appliances.
    e) LED streetlights.
    f) All other products that use LEDs such as in children's shoes, bicycle lights, etc.
4) Summary of what the FDA understands about the adverse health impacts of LED visible radiation:
    a) Seizures.
    b) Migraines.
    c) Panic attacks.
    d) Agitation.
    e) Nausea.
    f) Vomiting.
    g) Eye injury.
5) Summary of what the FDA understands about its mandate to communicate and assist federal agencies with developing regulations to protect the public from LED visible radiation:
    a) Department of Energy
    b) Department of Education
    c) Department of Transportation
    d) Department of Justice
    e) Access Board
    f) Centers for Disease Control
    g) Environmental Protection Agency
    h) Federal Highway Administration
    i) National Traffic Safety Administration
    j) Occupational Safety and Health Administration
    k) Federal Motor Carrier Safety Administration
    l) Federal Aviation Administration
    m) Consumer Product Safety Commission
6) Expected date for providing a decision on the petition.

We request this information from the FDA no later than the one-year anniversary of the submission of the petition.

Sincerely,

/s/ Mark Baker
President
Soft Lights Foundation
mbaker@softlights.org