Soft Lights Foundation

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June 13, 2023

BY EMAIL

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

Re: Petition FDA-2022-P-1151 Administrative Remedies Exhausted

Dear Patricia Kaufman,

This letter is to inform you that the Soft Lights Foundation has exhausted all administrative remedies to compel the FDA to approve petition FDA-2022-P-1151 and publish performance standards for LED products.

June 12, 2022 - The Soft Lights Foundation submitted citizen petition FDA-2022-P-1151 to the FDA to publish performance standards for LED products. 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.

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*."

March 21, 2023 – The FDA responded to an inquiry by Senator Maria Cantwell that the FDA was "working diligently" on the petition but provided no evidence to support the claim.

March 31, 2023 – Robert Ochs, Director, FDA OHT 8, responded to a citizen letter with the same "working diligently" claim, but provided no supporting evidence for that statement.

May 24, 2023 - Americans for Responsible Technology submitted a petition similar to FDA-2022-P-1151, requesting that the FDA comply with 21 U.S.C. 360ii and study and take action to minimize risk from exposure to non-ionizing electromagnetic radiation.[1] This petition has been assigned docket number FDA-2023-P-2115-0001.

[1] https://www.regulations.gov/document/FDA-2023-P-2115-0001

May 26, 2023 – The Soft Lights Foundation requested detailed information about the efforts of the FDA related to approving petition FDA-2022-P-1151. The FDA did not respond.

May 29, 2023 – The Soft Lights Foundation submitted a petition to the National Highway Traffic Safety Administration, requesting that the DOE liaise with the FDA and comply with 21 U.S.C. 360ii.[2]

May 30, 2023 – The Soft Lights Foundation submitted a petition to the Department of Energy, requesting that NHTSA liaise with the FDA and comply with 21 U.S.C. 360ii.[3]

June 5, 2023 – The Soft Lights Foundation submitted a petition to the Access Board, requesting that the Access Board liaise with the FDA and comply with 21 U.S.C. 360ii.[4]

June 13, 2023 – Exactly one year has passed since the submission of petition FDA-2022-P-1151 and the FDA has provided no evidence that the FDA has made any effort to comply with 21 U.S.C. 360ii or to approve petition FDA-2022-P-1151.

There are now multiple legal actions related to LED streetlights and the hazards these unregulated and unapproved devices pose to the public, such as:

1) New York State Public Service Commission, Case number 21-02623[5]
2) Soft Lights Foundation DOJ Request for Investigation.[6]
3) Alaska Human Rights Commission, Case ASCHR J-22-097.
4) Highlands, New York, Docket 2021-01543.

The petition to ban hazardous LED headlights is nearing 50,000 signatures.[7]

It is our understanding that:

- The FDA has stopped responding to inquiries about this issue.

- The FDA has not published any notifications to the public on the FDA's website about the hazards of LED visible radiation.

- The FDA has not established communication with the DOE, EPA, NHTSA, FHWA, Access Board, FMCSA, CPSC, FAA, OHSA, DOT, DOJ, CDC, or the Department of Education to develop performance standards for LED visible radiation, in violation of 21 U.S.C. 360ii.

- The FDA has not published 21 C.F.R. 1040.40 - Performance Standards for LED products.

- The FDA has not established a method for collecting reports of harm from exposure to LED visible radiation, despite requests by the Soft Lights Foundation to do so, and despite the numerous reports of harm being reported on social media and via other avenues.

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[2] http://www.softlights.org/wp-content/uploads/2023/06/NHTSA-Petition-to-Collaborate-with-FDA.pdf
[3] http://www.softlights.org/wp-content/uploads/2023/06/DOE-Petition-to-Collaborate-with-FDA.pdf
[4] https://www.softlights.org/wp-content/uploads/2023/06/Access-Board-Petition-to-Collaborate-with-FDA-1.pdf
[5] https://documents.dps.ny.gov/public/MatterManagement/CaseMaster.aspx?MatterCaseNo=21-02623&CaseSearch=Search
[6] https://www.softlights.org/wp-content/uploads/2023/04/LED-Discrimination.pdf
[7] https://www.change.org/p/u-s-dot-ban-blinding-headlights-and-save-lives

- The FDA has not notified Congress that the FDA is not in compliance with 21 U.S.C. 360ii and that LED products are a human health hazard.

Given the evidence provided above, the FDA has shown a willful disregard for the law and is acting recklessly and negligently, endangering the lives, and violating the civil rights of all Americans. The Soft Lights Foundation has now exhausted all administrative remedies with the FDA and is hereby notifying the FDA that the Soft Lights Foundation will be seeking remedies which may include Congressional hearings, investigations by the General Accountability Office and/or State Attorney Generals, and civil lawsuits.

Sincerely,

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