Gmail **Mark Baker <mbaker@softlights.org>**

FDA's Decision to Ignore Representatives Thompson and Pocan

Mark Baker <mbaker@softlights.org> Sun, Jun 16, 2024 at 1:17 AM
To: FDA Commissioner <commissioner@fda.hhs.gov>
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Dear Robert Califf, Commissioner, FDA,

I am a constituent of Representative Mike Thompson of California. Representative Thompson wrote you a letter on July 28, 2023, requesting that you "*provide full and fair consideration to prescribing performance standards for automobile LED headlights that would address the health and safety issues related to excessively bright headlights*." (https://www.softlights.org/wp-content/uploads/2023/07/Thompson.pdf). You were sent a similar letter from Representative Mark Pocan on October 3, 2023. (https://www.softlights.org/wp-content/uploads/2023/10/LED-headlights-letter-10-3-23.pdf).

You have not responded to the letter from either Representative Thompson or Representative Pocan.

On May 24, 2024, the FDA responded to four Soft Lights Foundation petitions to regulate LED products, including automobile LED headlights, by denying all four petitions. However, nowhere in the May 24th letter did the FDA describe any consultations with the National Highway Traffic Safety Administration on Representative Thompson's and Pocan's requests regarding performance standards for LED headlights. The failure of the FDA to consult with NHTSA on the regulation of automobile LED headlights is a violation of 21 U.S.C. 360ii(a)(6). The FDA has unilaterally decided that no performance standards are necessary for LED headlights and has ignored the requests of two members of Congress to "provide full and fair consideration" to the issue.

I am deeply and adversely impacted by LED headlights, and my health and safety have been harmed by the failure of the FDA to regulate LED headlights. This issue likely impacts hundreds of millions of other individuals. The harm to me is so severe that I filed a Pro Se lawsuit against the FDA on January 22, 2024, requesting that the court order the FDA to comply with 21 U.S.C. 360ii(a)(6), among other statutes. (https://www.softlights.org/wp-content/uploads/2024/01/Mark-Baker-vs.-FDA_filed.pdf).

On June 11, 2024, Representative Thompson sent a letter to the House Energy and Commerce Committee requesting a hearing on NHTSA's failure to protect the public from the hazards of LED headlights. (https://www.softlights.org/wp-content/uploads/2024/06/Mike-Thompson-Hearing-Request-re-Overly-Bright-Automotive-Headlights.pdf). Implicit in Representative Thompson's letter is the failure of the FDA to respond to Representative Thompson's July 28, 2023 letter to the FDA and the FDA's failure to consult with NHTSA on the issue of regulating LED headlights.

The purpose of this letter to you, Commissioner Califf, is to request that you respond to Representatives Thompson and Pocan and detail the FDA's justification for not consulting with NHTSA, and the FDA's unilateral decision to not publish performance standards for automobile LED headlights. In this email, I have copied your attorney, Samuel Balingrud of the US DOJ, the House Energy and Commerce Chair and Ranking Member, and Sophie Shulman, Acting Director of NHTSA.

Sincerely,

Mark Baker
President
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